Final Technical Report
on the research results achieved between 1 November 2017 and 31 May 2023
in the project No. K-125263 supported by the NRDIO

The research on optimally parameterised interaction strategies for robot-mediated active-guided motion therapy at spastic hemiparetic upper limbs began in the first year as planned in the description of work. The clinical team worked on the neuroplasticity models, the outcome measures and the recommendations for the technical system update. The technical team worked on the system update, the design of the interaction controller, and the design of the isometric force test battery. Suddenly, the first force majeure event out of the six force majeure events occurred during the project's lifetime. Table 1. summarises the landscape transformation series of the force majeure events hitting the project.

Table 1. Six Force Majeure events and the implemented contingency actions

Year	Force majeure event	Contingency action through grant amendment
2018	Mihály Jurák, the key and only software developer of the REHAROB system, suddenly passed away.	The tasks of Mihály Jurák were taken over partly by researcher Andras Juhász and partly by students György Herke and Tamás Patai.
2018	From 2000 to 2017, the constructive partnership with the robot provider changed abruptly. To our surprise, ABB AG withdrew from any further cooperation, citing robots' intended medical use.	The lead researcher of the co-project No. K 125357 held talks with 22 leading collaborative robot manufacturers at the world's largest robotics trade fair, Automatica 2018 in Munich. He prepared a 25-page market survey and conducted further narrower negotiations. The consortium chose Universal Robots UR5e to replace ABB's IRB140 robot arm. Financial resources were available in the grant for procuring one new robot arm through grant amendment. Own funding was necessary to raise the costs of the second robot arm, the planned two robotic fingers and the robot controller. The 2D servo platform was omitted.
2019	The public procurement of the second robot arm of the REHAROB system from our own financial resources lasted until September 2021!	The co-project No. K 125357 development team had temporary access to the UR10e robot purchased at another department of BME, the Department of Applied Mechanics. The design and development of the REHAROB 3.0 upper limb rehabilitation robot system did not stop. An extension for the grant duration was requested.
2020	Outbreak of the COVID-19 pandemics: primary effect.	BME, the host institute of the co-project No. K 125357, was closed temporarily due to the pandemic restrictions. Both the staff and students were requested to work online in their homes. Most of the technical development, however, requires in person contributions from the development team in the laboratory. An extension for the grant duration was requested.
2021	Outbreak of the COVID-19 pandemics:	Due to the broken supply chains, DARPAMotion Ltd, the subcontractor of the principal investigator's host institute, could

	secondary effect.	not procure an SMD component for 12 months. An extension for the grant duration was requested.
2022	Clinical trial approval, according to MDR	The introduction of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices in Hungary caused only the medical device manufacturer to act as applicant/sponsor of the Clinical Trial. In Europe, a research organisation, that can no longer act as a manufacturer due to the introduction of MDR, cannot conduct clinical trials.

Grant underspending:
Due to force majeure events, the plan of research tasks for the clinical side had to be revised, i.e. among others, neither the clinical trial phase A nor phase B could be conducted, which led to 57.2 % underspending of the project grant No. K-125263. Due to the elongated technical developments, the co-project grant No. K-125357 was fully spent, whereas large amounts of own funding were devoted to the research work. The results of the project must be evaluated in light of these facts.

Progress of the research and results of the project No. K-125263 (clinical side):
The principal investigator and his team presented in a 103-page study and a conference paper the methods suitable for examining and influencing neuroplasticity in stroke patients. Conclusions were drawn from the review of scientific publications on robot-assisted therapy, leading to recommendations on the specifications of the REHAROB upper limb rehabilitation system. The results were published in the journal REHABILITÁCIÓ: A MAGYAR REHABILITÁCIÓS TÁRSASÁG FOLYÓIRATA.

While the new REHAROB 3.0 robot platform was designed and developed, the current REHAROB 2.0 platform was kept for conducting an isometric force test battery to investigate the changes in isometric force and torque during the rehabilitation of patients with post-stroke hemiparesis. The measurements were executed in cooperation between the K-125263 and K-125357 teams (at least one physiotherapist and one engineer were present at the measurements). Force and torque were measured by the two 6-axis force-torque sensors of REHAROB system. 10 healthy and 20 hemiparetic subjects were included (9 male, 11 female, mean age: 58.75±13.38 years), and each subject had three measurements. The investigation plan was approved by the Ethics Committee of OORI. Each participant signed informed consent. According to the results at some patients whose Fugl-Meyer points were increased between the first and last measurements, the ability of muscle force and torque generation were also increased. The OORI+BME joint team presented the results of the project by posters at RehabWeek 2019 conference (Toronto, Canada), at the 38th Congress of Hungarian Rehabilitation Association (Debrecen, Hungary), and at the 22nd ESPRM conference.

One of the REHAROB 3.0 rehabilitation robot system innovations is the use of real objects for motor re-learning. The therapeutic advantages of using real objects over a virtual object in robot-assisted movement rehabilitation were presented at the International Congress of European Forum for Research in Rehabilitation 2021.

The final clinical task of the K-125263 team in the reporting period was to perform co-design and co-development actions on the REHAROB 3.0 upper limb motion. From January to May 2023, three

physicians and six physiotherapists in groups of two and three professionals performed half-day in-person testing of the prototype system. The conclusions and recommendations were summarised for the post-project exploitation phase.

Progress of the research and results of the co-project No. K-125357 (technical side):

Initial results on the new rehabilitation robot platform design and the isometric force measurements were presented in the Scientific Students' Associations Conference:

• Tamás Szigeti, György Herke: Felső végtag antropometriai paramétereinek meghatározása és mozgatásának modellezése két robotkaros gyógytornáztatás esetében

In this study we defined the length and position parameters of the human upper limb (shoulder-upper arm-elbow-wrist-hand) from previously recorded measurement data and visualise these motions. This work was published later in a 4-page conference paper format and presented in an international conference (XXVIII. Nemzetközi Gépészeti Konferencia – OGÉT 2020).

Currently, it is the therapist who selects and customises the patients' task in post-stroke, robot-mediated rehabilitation. It would be an important step forward if rehabilitation robots would be able to support the therapist's decision by automatically performed measurements.

• Marcell Doros: Izometriás erőmérés és hőtérképezés, mint döntéstámogatási lehetőségek a stroke utáni rehabilitáció során végzett robotos terápiában

In this study, it was examined whether simultaneous isometric force/torque measurements and heatmapping are advantageous in decision-making and control of the therapy.

The BME team spent effort on the mechanical, electrical, and control design of the new Universal Robots based REHAROB 3.0 dual-robot rehabilitation platform. Indeed, the research and development effort required more effort than was provided by the grant, so BME launched and completed a number of BSc student final projects: Dávid Szabolcs: Development of a dummy limb for testing of an upper limb rehabilitation robot system (subm: May 2021); Al-Absi Ghassan Mohammed Ahmed Kaid: Safety inspection of upper limb's anatomical joints during rehabilitation therapy done by cobot system (subm: May 2021); Ákos Németh: Object grasping detection with force sensing resistor integrated into the rehabilitation robot's hand (subm: Dec 2021); Ákos Racs: Design and development of a 3D printed, forearm-elbow orthosis with flexible, self-closing mechanism for a robotic physiotherapy system module (subm: May 2021); Renáta Kiss: Design and development of a 3D printed, lower arm-upper arm hinged orthosis for a robot-assisted physiotherapy system module (subm: May 2021); Zsolt Petró: Risk Assessment for the Design Process of a Rehabilitation Robot System (subm: Dec 2020). Despite the numerous irregularities, the BME team finished the development and technical testing of the REHAROB 3.0 rehabilitation robot system. The results were presented in two WoS IF journal papers, and a third WoS IF journal paper is under submission.

An unplanned significant additional result of the research was the development of an instrumented artificial arm prototype suitable for testing a general rehabilitation robot (Figure 1.). The result was presented in the form of a 6-page conference paper format at the International Conference of Rehabilitation Robotics 2022 and in WoS IF journal paper.

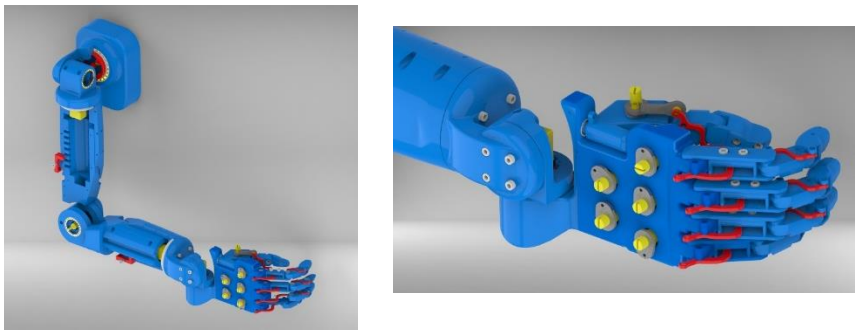

Figure 1. Instrumented dummy limb during testing of the early REHAROB 3.0 prototype (2021) and the extension of the dummy limb with a dummy hand (2023)

Exploitation of the results:

The Principal Investigator of the project grant No. K-125263 in partnership with the Slovenian University Rehabilitation Institute submitted an SNN_22, and, after its rejection, an SNN_23 bilateral NRDIO-ARRS proposal in the real vs. virtual object topic.

In 2020 OMINT-NIMR, BME and DARPAMotion Ltd. submitted an H2020 COVR Award Proposal titled: Two-finger robotic device for hand rehabilitation after stroke. Unfortunately, the proposal was not selected for funding.

BME submitted a HORIZON-CL4-2022-DIGITAL-EMERGING-02 proposal titled: Physically Intelligent Collaborative Robot. The proposal was rejected.

The development of the REHAROB 3.0 movement rehabilitation robot was guided by the objective of showing breakthrough innovations in its structure compared to its known market or research competitors. The goal was fully achieved because there is no known upper limb movement rehabilitation robot that 1) exercises the entire upper limb holistically, i.e. moves all anatomical joints at the same time, 2) carries out neuromotor re-learning by reaching and grasping a real object by practicing everyday activities, 3) builds the system from industrial collaborative robots. The functional prototype met the expectations during the participatory development. As a follow-up action the research will continue to motorise the instrumented dummy limb and hand, forming a standalone spin-off project result.

In August 2023, we turned to BME Center for University-Industry Cooperation (FIEK), BME Research, Innovation and Development Gateway Entity (BRIDGE) regarding the utilisation of the project's results. BME FIEK BRIDGE assessed the REHAROB system as suitable for exploitation on the basis of the submitted documents. The primary direction of exploitation is the start-up company founding,

and the secondary utilisation direction is selling the know-how to a professional investor. By October 24, 2023, a Hungarian-language one pager, an English (Figure 2.) and a Hungarian-language A4 flyer and an English-language A5 flyer (Figure 3.) have been completed. Business value proposition, market research, Business Model Canvas and 3 min Pitch are being prepared. The project's principal investigator distributed 60 printed flyers at RehabWeek 2023 in Singapore in September 2023.

Budapest University of Technology and Economics

REHAROB activities of daily living (re)trainer

For about 30 years, rehabilitation robots have been helping physiotherapists with their high-load and repetitive neurorehabilitation movement therapy tasks. Different types of rehabilitation robots are used for moving different body parts, for various phases of a patient's recovery, and for moving the proximal or distal anatomical joints. Rehabilitation robots can have an exoskeleton or end-effector structure. All current upper limb rehabilitation robots interact with the patient through a virtual environment interface (gaming). All current upper limb rehabilitation robots are custom-developed by their manufacturer.

SOLUTION

To keep product costs low, REHAROB uses two mass-produced industrial collaborative robots to move the elbow and hand and two custom-developed robot fingers to move the fingers of the hand. In terms of its structure, REHAROB is unique, as it applies four end-effectors (RACA standard: actuated point) to move the entire upper limb. With the master-slave and admittance controls developed by us, we maintain coordination between the four end-effectors, thus achieving the natural movement of the exercised upper limb. REHAROB (re-)trains carefully selected seven tasks from eating, personal hygiene, communication, transport and shopping activities of daily living. Patients are assisted to grasp and move real physical objects: glass, bottle, basket, book, hairbrush, phone, door handle. REHAROB has been developed based on 23 years of R&D experience in rehabilitation robotics and two clinical trials, considering the requirements necessary to meet CE and FDA certifications. REHAROB can be plied effectively in the acute and chronic neurorehabilitation of patients with stroke and other neuromotor impairments.

TRL 4 Prototype validated in the laboratory.

SEEKING

Rehabilitation robot or medical device manufacturers who may be interested in licensing or purchasing REHAROB technology, designing and producing a mass-produced version of REHAROB, further developing control and user software (physiotherapist and patient), sponsoring clinical trials according to MDR, conducting medical certification, and in the commercial exploitation.

ADVANTAGES

- Synchronous exercising of the entire upper limb. The anatomical joints: shoulder, elbow, wrist, hand, and fingers are moved simultaneously, just as they do when performing everyday tasks.
- Practicing seven Activities of Daily Living by grasping and moving real objects.
- Utilization of industrial collaborative robots for healthcare tasks.

CONTRIBUTIONS FROM:

- National Institute of Locomotor Diseases and Disabilities, Hungary
- DARPAMotion Ltd., Hungary

INFORMATION, PUBLICATIONS

http://oori.bme.hu/page4.html

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Tavaszi, I., Tóth, A., Pilissy, T., Bauer, M., Hodosán, Z., Stépán, G., Magyar, B., Fazekas, G. "Robotic Fingers in Reach-to-Grasp Tasks of Rehabilitation", Periodica Polytechnica Mechanical Engineering, 66(4), pp. 273–281, 2022. https://doi.org/10.3311/PPme.17484

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Figure 2. English-language A4 REHAROB flyer

Figure 3. English-language A5 REHAROB flyer

Comment on the ethical approval procedure for a clinical investigation involving humans:

Since the start of the project in 2017, the ethical approval procedure for clinical trials involving humans has changed substantially In Hungary. Our opinion applies to those studies in which the effectiveness of a prototype of a medical device created as a result of a basic research project or a university diploma or PhD thesis would be assessed with the involvement of humans. We see that in Hungary, ethical approval of all medical research aimed at clinical investigation of software or hardware, regardless of its basic or commercial research nature, belongs to the National Institute of Pharmacy and Nutrition (NIPN). NIPN closely follows the requirements of the MDR, which medical device manufacturers with adequate legal, standard, manufacturing, documentation and financial capacity can only meet. The public and basic research performers, therefore, have no choice at all to ethically approve their clinical investigation plans. Our opinion is justified by grant No. 2019-2.1.2-NEMZ-2019-00006 in which ethical approval could not be obtained from NIPN after a year with application submission, resubmission, and responses to all deficiency notices. Summary: Large part of Hungarian clinical trials cannot be carried out due to legislation irregularity.

All in all, the research can be considered successful; we fulfilled our commitments modified several times in the contract due to force majeure events. I would like to thank NRDIO for financing the research project.

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