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Why effectiveness of robot-mediated neuro-rehabilitation does not necessarily influence its adoption?

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***Abstract*— This paper discusses the reasons why evidence of clinical effectiveness is not enough to facilitate adequate adoption of robotic technologies for upper-limb neuro-rehabilitation. The paper also provides a short review of the state-of-the-art of these technologies. In particular, the paper highlights the barriers to the adoption of these technologies to the markets in which they are, or should be, deployed. On the other hand, the paper explores how low rates of adoption may depend on communication biases between the producers of the technologies and potential adopters. Finally, it is shown that, although technology-efficacy issues are usually well-documented, barriers to adoption also originate from the lack of solid evidence of the economic implications of the new technologies.**

***Index Terms*—Rehabilitation robotics, robot-mediated post-stroke rehabilitation, end-point manipulator, exoskeleton, cable suspensions, effectiveness, technology adoption, economic barriers, dissemination.**

I. Introduction

STROKE is the major cause of adult long-term disability in Europe and many other countries, and strains national services and related costs. In about 85% of cases, stroke causes hemiparesis resulting in impairment of the upper limb and disabilities in performing activities of daily living, with consequent medical and social care consuming a huge amount of healthcare resources [1]-[8].

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In recent years, several researchers have shown that the quantity, duration, and intensity of training sessions are important variables in relearning motor skills and in changing the underlying neural architecture. In fact, looking at the effects of different intensities of physical therapy treatment, a significant improvement in activities of daily living as a result of higher intensities of treatment has been reported [9]-[10]. When traditional therapy is provided in a hospital or rehabilitation centre, the patient is usually seen for one-hour sessions, once or twice a day. For this reason, the possibility of increasing the efficacy of the rehabilitation by exploiting the potentialities of robot-mediated therapies is becoming more and more popular around the world.

Robot-mediated neuro-rehabilitation (R-NR) has been proposed to support physicians and physical therapists in providing high-intensity therapy, consisting of repetitive movements of the impaired limb. Robots have been introduced as a solution to allow patients to receive a more effective and stable rehabilitation process, and therapists to reduce their workload. Robots can also offer reliable tools for assessing the patient's progress and recovery by measuring physical parameters, such as speed, direction, and strength of patient residual voluntary activity. Robot-aided rehabilitation is slowly being accepted by the therapists' community as being as good as or even better than manual therapy [7], [11]-[17].

The effectiveness of R-NR is supported in an increasing body of literature (as shown in the next sections). This is particularly true for R-NR for upper-limb functions, which recent studies showed to be quite effective and potentially very promising [15], [18]. Nevertheless, its rate of adoption is far behind the rate we could expect considering the potential positive implications connected to the use of the technology. Turchetti *et al.* [19] underlined the positive relation between severity of stroke, related social costs and effectiveness gain derived from technological innovation in rehabilitation. For highly severe stroke the balance between costs and effectiveness may also increase the cost-effectiveness ratio of robot-assisted rehabilitation. The high potentiality of robot-assisted rehabilitation is also stressed by Krebs *et al.* [20] who highlight the importance of multiple robots for therapies to different limb segments.

In addition, studies [20] that focus on the economic dimension and the impact of the technology, show - among the benefits - a good reduction of time for rehabilitation, increasing productivity of patients, that means a drastic

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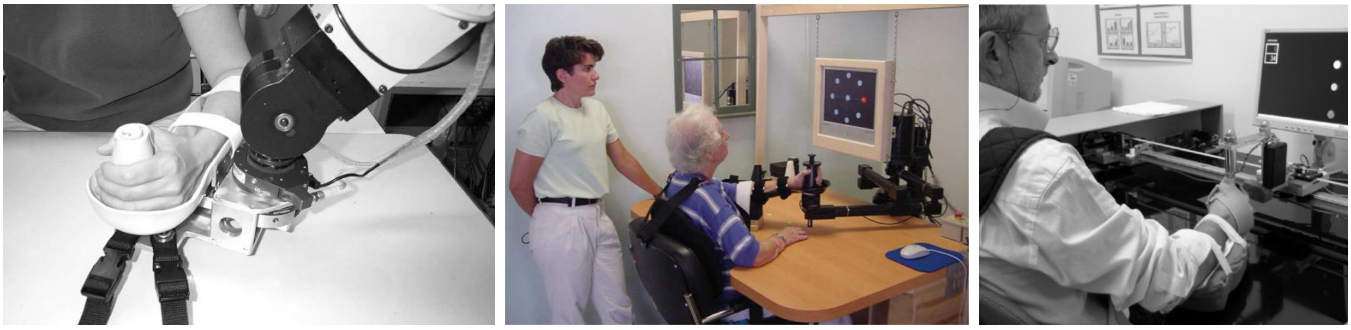

(a) (b) (c)

Figure 1. State-of-the-art end-point manipulators for upper-limb rehabilitation. (a) MIME (adapted from [44]). (b) MIT-Manus (adapted from [45]). (c) MEMOS (adapted from [46]).

reduction of indirect costs associated to productivity and workdays lost because of the rehabilitation. For elderly patients indirect benefits are associated to caregivers' reduction of workdays for assisting their relatives.

The aim of the paper is to propose and discuss the reasons why evidence for clinical effectiveness are not enough to facilitate an adequate *adoption* of robotic technologies for neuro-rehabilitation. The topic addressed would be of any interest if the rate of adoption of technological innovation was proportional to its actual effectiveness in solving new problems or in solving old problems in a more effective and/or efficient way. But this is not the case.

The paper focuses on robot-mediated rehabilitation technologies for upper-limb impairment as a case study following recent clinical evidence. It is worth noting that in this study – with reference to the expression *barriers to the adoption of robotic technologies for neuro-rehabilitation* - we prefer the term *adoption* (i.e, the decision to commit to and initiate an evidence-based intervention [21]-[23]) to the term *diffusion* (i.e., the passive and unplanned spread of new intervention [22]-[24]), since *adoption* assumes a pro-active perspective. In particular, *adoption* often is also considered a synonymous of *acceptance*, the latter being a pre-requisite for directly or indirectly affecting the adoption of the technology by the health care organizations. In other terms, acceptance is a necessary, still not sufficient condition for the final technology adoption. Finally, a related concept mentioned in the conclusions of the article is *dissemination*, i.e., the active approach of spreading evidence based-intervention [21], [24]-[25].

Barriers to the adoption of these technologies can be found in the characteristics of the market in which they are or should be deployed. The healthcare market, in fact, is a market where introducing a new technology often means to radically reorganize processes and protocols of care, reimbursement schemes, redesign efforts and responsibilities in the service providers and the other stakeholders involved [26]-[28].

Low rates of adoption may also depend on communication biases between the technology producer and the potential adopters. Other barriers originate from the lack of a solid evidence about the economic implications of the new technology, while the perspective on the technical/efficacy issues is usually very well documented. Without a clear and scientifically-based analysis of the potential economic and societal burden of the new technology, a short-run perspective - where the current cost of the technology (either a new drug or a new medical device) is the most important driver for decision making on technology adoption - risks to prevail [29]-[34]. In a context where the continuous growth of healthcare costs raises serious concerns about the economic sustainability of the system, in fact, the effectiveness of a new technology is a necessary but not sufficient condition for its adoption [19], [35]-[39]. The guiding principle in the prioritizing process that public and private payers are called to implement is more and more frequently the short term saving target defined by actual budget constraints.

The paper is structured as follows. After a quick overview of the main robotic platforms for upper-limb neuro-rehabilitation and the evidence showing their effectiveness, we present the most relevant barriers to adoption of new technologies, and robot-technologies in rehabilitation. Barriers are identified by applying a typical paradigm of *analysis of barriers to technology adoption* to the specific case of upper-limb R-NR [22]: some barriers are shared also by other technology domains in- and out-side the health sector, while some other barriers are more specific of the upper-limb R-NR sector. In particular, some reasons that could explain the relatively low rate of adoption of robot-technology rehabilitation with respect to its documented effectiveness are cited and explained. A final paragraph draws the conclusions of our contribution.

II. Robots for Upper-Limb Neurorehabilitation

Appropriateness and effectiveness of robotic technologies in rehabilitation are very well documented in the scientific literature, that highlights clear comparative advantages with respect to traditional rehabilitation procedures in terms of clinical and bio-mechanical measures. Prange *et al.* [6], who reviewed studies on the effectiveness of robot-aided therapy for hemiparetic arms, claim that while robot influence in functional activities is controversial, the effectiveness of robot in improving short and long run motor control is a better solution than traditional technology or therapy.

The positive gain of using robot for rehabilitation is more evident as the severity of stroke-related deficiency increases: it is the same conclusion of Turchetti *et al.* [19].

This is a common trend for many devices developed for upper-limb rehabilitation, regardless they are endpoint manipulators [14], [40]-[52], cable suspensions [53]-[57], or powered exoskeletons [58]-[83]: a quick survey of major

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results of research activities in the state-of-the-art is reported hereafter.

A. *End-point manipulators*

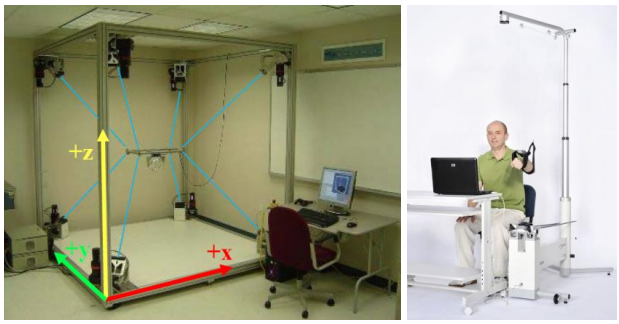
End-point manipulators were the first robots to be introduced in the literature, and are - by far - the ones which have been involved in the highest number of both single- and multi-centre clinical trials (Figure 1).

Among many, relevant case studies of endpoint manipulators are: the MIME [40]-[43], which was the first attempt of using an industrial robot for robot-mediated neuro-rehabilitation purposes; the MIT-MANUS [13]-[14], [47] which was the first system to be available on the market: it is now commercialized by the Interactive Motion Technologies, Inc, (Cambridge, MA) with the name InMotion^2 Shoulder-Elbow Robot, at a cost of approximately 40-50 k$ (USD); the Bi-Manu-Track [48]-[50], which is a representative example of manipulator for bi-manual training; and - eventually - the MEMOS [51]-[52], which was the result of one of the first research activities aiming at developing a cost-effective system for both hospital and home neuro-rehabilitation sessions.

The MIME, namely "Mirror Image Movement Enhancer", consists of a six degrees of freedom (DOF) robot manipulator (PUMA 560, Staubli Unimation Inc, Duncan, South Carolina), which applies forces (assistance or resistance as needed) to a patient's forearm by means of a handle that is connected to the end-effector of the robot. Peculiarity of this robot is the fact that it was based on the use of a 3-D workspace industrial robot, purposively adapted for use in clinical settings. This device could work in different modalities: to either move the limb of a patient along a preprogrammed trajectory, allow the subject to trigger the movement with volitional force, provide a viscous resistance in the direction of the desired movement, or allow the patients to execute bimanual tasks. This system undertook a clinical trial with 13 stroke subjects and showed that robot-aided therapy had therapeutic benefits.

The MIT-MANUS was instead introduced as a 2-DOF manipulator that could allow the patient to execute reaching movements onto a horizontal plane. Peculiarity of this robot was its inherent backdrivability (i.e., its inherent minimum resistance to the human motion), given by its parallel structure and the use of direct-drive motors: the robot could also guarantee a safe, stable and compliant human-robot interaction in all working conditions. Similarly to the MIME, the MIT-MANUS could move, guide or perturb the movement of patient's upper limb and record motions and mechanical quantities such as the position, velocity, and interaction forces applied. Finally, the MIT-MANUS was the first robot to introduce the use of a personal computer to challenge the patient with game-like exercises and provide him or her with feedback on the execution of the rehabilitation task.

The MIT-MANUS is by far the robot for upper-limb rehabilitation tested by the highest number of patients. A major conclusion deriving from both past, still single-center, and recent, multi-center studies, is that prolonged sessions of robot-based therapy can work better than usual therapy [15]: in other terms the added value introduced by the robot-mediated therapy is the possibility to carry out longer and more intensive rehabilitation therapies without overloading the therapists and while ensuring a quantitative assessment of the rehabilitation progress.



(a) (b)

Figure 2. State-of-the-art cable suspensions for upper-limb rehabilitation. (a) MACARM (adapted from [55]). (b) ARMEO Boom (source: http://www.hocoma.com/).

The BI-MANU-TRACK, designed by Hesse *et al.* [48], was introduced with the ultimate goal to investigate the effectiveness of bi-manual therapeutic sessions. In particular, the robot was designed to train distal arm movements by practicing both bilateral elbow pronation and supination and wrist flexion and extension. Similarly to previous devices, this robot allowed both passive or active training modalities, and was object of an extensive clinical use involving forty-four sub-acute post-stroke patients [48]-[50]. In this case, robot-mediated rehabilitation was also compared to electromyography-initiated electrical stimulation (ES) rehabilitation. Also in this case, results showed that robot-based therapy led to better outcomes compared to conventional therapy, mostly because of the greater number of repetitions and the bilateral approach: in other terms, this study further proved that the R-NR can be more effective than conventional therapy thanks to the higher-intensity of the treatment, with benefits for the patient in carrying on activities of daily living.

The "MEchatronic system for MOtor recovery after Stroke (MEMOS) was purposively designed to foster the development of a cost-effective robot for neuro-rehabilitation. The idea was that a relatively low-cost (in the range of 5-to-10 k€, EUR) device could facilitate the adoption of robot-mediated therapy protocols in clinical practice, and – with a longer term vision – to setup telerehabilitation scenarios. In order to achieve such a goal, the MEMOS was developed by mostly exploiting "off-the-shelf components", and thus mounting a few custom parts. The MEMOS allowed a horizontal, 2-DOF workspace: instead of a parallel mechanism, the robot had a planar, Cartesian architecture, implemented by means of two orthogonal linear sliders powered by gear-head DC motors. Also the MEMOS underwent extensive clinical trials, involving in total 50 (both acute/subacute and chronic) patients [51]-[52]: results confirmed that robot-mediated therapy could favor recovery of the motor functionality, with acute/sub-acute patients showing more significant therapeutic benefit deriving from the use of the robot.

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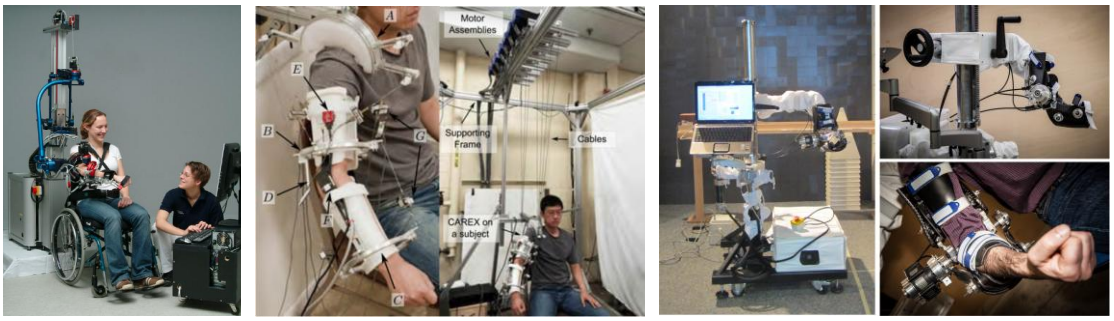

(a) (b) (c)

Figure 3. State-of-the-art powered exoskeletons for upper-limb rehabilitation. (a) ARMIN (adapted from [70]). (b) CAREX (adapted from [77]). (c) NEUROExos (adapted from [82]).

B. Cable suspensions

While experimentation of endpoint manipulators produced a quite considerable amount of clinical results, leading to a mature awareness of their effectiveness in NR scenarios, both cable suspensions and exoskeletons are still relatively "young technologies", mostly experimented in laboratory or in small-scale single-center clinical trials. However, as explained in the following analysis, both cable suspensions and exoskeletons are proving to be effective solutions for R-NR, and in some cases they also reached the market: this is the case of some of the products commercialized by Hocoma, such as ARMEO Power (cost of approximately 250 k€, EUR), ARMEO Spring (cost of approximately 40 k€, EUR), and ARMEO Boom (cost of approximately 30 k€, EUR).

Cable suspensions were mostly investigated as a solution to address the construction of a light-weight, low-inertia mechanical structure connected to the human limb, with the ultimate goal of minimizing the loading effect of the robot on the human joints (Figure 2). Indeed, cable suspensions exploit *tendon cables* driven by remote actuators to apply force/torque on a limb segment, through either a orthosis worn by or a handle grabbed by the patient. By far, the two most relevant examples of cable suspensions are: the MACARM [54]-[55] which was the first case reported by the literature, and the Freebal [56]-[57], which reached the market with the name Armeo Boom (a product specifically conceived for patients with moderate movement impairments).

The MACCARM (namely "Multi-Axis Cartesian-based Arm Rehabilitation Machine") was designed by Mayhew *et al.*, and is a cable-driven: it is composed of an array of 8 DC motors mounted at the corners of a cubic support frame that provide a centrally located end-effector with 6 active DOFs. At the best of our knowledge, no clinical studies were carried out with the MACARM. Indeed, the work of Beer *et al.* [55] was devoted to experimentally assess the performance of the MACCARM system in terms of actual range of motion and accuracy of the position/force control system.

The Freebal system (developed at the University of Twente, The Netherlands) consists of an overhead sling suspension system which provides an adjustable amount of arm weight support and allows patients to perform self-directed, free movement exercises of the impaired arm in a large three-dimensional workspace. Freebal can provide constant and partial-to-full gravity compensation of the arm weight without any actuator or sensor. Contrarily to the MACCARM, Freebal was tested in a clinical study involving 8 post-stroke patients [57]. The main outcome of this study was that this kind of systems can be used to increase the intensity of the training: indeed, as a consequence of the arm weight compensation, patients could benefit of a reduction of the muscle effort, and thus prolong the training sessions.

C. Upper-limb powered exoskeletons

Finally, powered exoskeletons were introduced as a solution to provide motion assistance independently to each user's joint (Figure 3). Despite their higher system complexity, exoskeletons – by offering the possibility of individually assisting upper-limb joints - were considered to better retrain correct physiological musculoskeletal synergies, minimizing and controlling any compensatory movement [72]. A powered exoskeleton for post-stroke physical rehabilitation is a non-portable mechanical device that is anthropomorphic in nature, is "worn" by the user, and fits closely to his or her body [80]. Desirable features of exoskeletons to enhance patient comfort are: anthropomorphic range of motion (ROM), large physical human–robot interaction (pHRI) area, an actuation/control system which allows safe execution of both *robot-in-charge* and *patient-in-charge* modes.

In the literature there are several exoskeletons, however, relevant case studies are: the ARMin [66]-[67], [70], which is the only multi-DOF powered exoskeleton which reached the market (with the name ARMEO Power), the L-Exos [61]-[62], which is one of the most performing 7-DOF upper-limb exoskeletons, the CAREX [73]-[77], and NEUROExos [80]-[81], the latter ones being recent devices proposing interesting solutions for enhancing a comfortable human-exoskeleton interaction.

The ARMin was developed at the ETH Zurich and is a haptic display with a semi-exoskeleton kinematics, with 4 active (3 for shoulder and 1 for elbow) and 2 passive DOFs. A subsequent version, ARMin II, has instead 6 DOFs, and has a modular design, which allows the robot to be configured in various combinations of proximal and distal arm training modes. Overall, ARMin – regardless its version - can work in three therapy modes: passive mobilization, game therapy, and task-oriented training. The functionality of this device was assessed by clinical results from studies involving overall 14 patients, before reaching the market with the name ARMEO

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Power. One of the limitations of ARMin is its overall high inertia of the moving parts, if compared to other devices such as the L-exos, whose design attempted to reduce movement inertia of the exoskeleton by remotely locating the actuators.

L-EXOS (Light Exoskeleton) is a force-feedback exoskeleton for the human arm, designed as a wearable interface, capable of providing a controllable force at the center of user's hand palm with high performance, in terms of backdrivability and low inertia. The peculiar characteristics of this exoskeleton are: its inherent low impedance and the high payload. The first tests of L-Exos with patients showed that the robot neither hindered the patient movement nor caused uncomfortable postures occurring. On the other hand, CADEN-7 (namely "Cable-Actuated Dexterous Exoskeleton for Neurorehabilitation") is a versatile human-machine interface with low inertia, high stiffness links, and backdrivable transmission means with zero backlash. The design achieves full-workspace range of motion, as requested to accomplish activities of daily living, for the glenohumeral, elbow, and wrist joints. Unfortunately, despite its interesting design, in the literature no clinical study is reported with CADEN-7.

By introducing innovative mechanical solutions, CAREX and NEUROExos were designed to maximize user comfort. In particular, CAREX was the first cable-driven exoskeleton that experimentally demonstrated the possibility to achieve desired push/pull forces on the hand without a rigid-link structure. Indeed, given the complete absence of bar-like linkages CAREX does not require any link length adjustment to match user anthropometry and its kinematics inherently avoids issues deriving from possible human-robot joint axes misalignment. NEUROExos was presented as an elbow powered exoskeleton designed for post-stroke rehabilitation which ensures maximum comfort and safety to the patient, thanks to three innovative solutions: double-shelled links, with a wide pHRI area to minimize the pressure on the skin, a 4-DOF passive mechanism that unloads the elbow articulation from undesired loads by ensuring the alignment of human and robot joint axes, and a biomimetic inherently compliant actuation system.

D. Remark

Although with a different level of maturity (high for endpoint manipulators, and gradually increasing for cable suspensions and exoskeletons), this short review of the state of the art of the robotic technologies for upper-limb rehabilitation clearly showed that these technologies are effective and already a reality in many circumstances. Therefore, the question that arises is: why these technologies are still very much under-diffused and neglected in the clinical practice? The next two sections will provide some hypotheses for the status quo.

III. ADOPTION OF ROBOTIC TECHNOLOGIES IN NEURO-REHABILITATION

Rates of adoption of robotic technologies in rehabilitation are very low. Data on adoption and trends in the market for robotic technologies in rehabilitation are not easily available (and it may be a proof that the rate of adoption of these technological solutions is very low). However, indirect indications of the market dimension and adoption of robot solutions for rehabilitation may come from market leaders and data on adoption of their products.

Hocoma, one of the worldwide market leader in rehabilitation robotics (Hocoma, a spin-off of ETH Zurich), has more than 500 Lokomats (walking robots) and 100 Armeos (arm robots) adopted in renowned rehabilitation and research institutes around the world [84]-[85]. Indeed, on 2012, Hocoma reported a positive development and achieved profitable results in all its business ventures: the 2012 turnover was about 25 M€, resulting in growth of 13% with respect to the previous year [86]. Another interesting case study is Tyromotion GmbH, a recently founded company which is active on the market with five products, among which Amadeo®, Diego® and Pablo® are advanced robotic platforms for the upper-limb rehabilitation [87].

These data illustrate the state of the art of the adoption of these technologies in the market and in the clinical practice. In most of the medical technologies segments, we observe a scale of revenues of hundreds of millions USD. One of the largest companies in the rehabilitation robotics business has revenues in a scale of tens of millions of USD.

There are some structural reasons that could explain this phenomenon. A first reason is that the application of robot technology to rehabilitation is relatively recent, although a first application of rehabilitation robotics dates two decades ago for neurological disorder, but with scopes and use of technology that were completely different from the actual ones [88].

The other reasons are the inherent barriers of the commercialization of new products, from the R&D phase to their intended market [89]; these barriers can be classified into technological, behavioral, organizational, and economic variables [38]-[39], [90].

A. Technological limits, capabilities, and characteristics

Technological barriers to adoption of innovations include the set-up of the innovation, ease of use, level of training necessary for caregivers to master the technology, and the anthropomorphic design of the product. As innovations, especially medical technological innovations, are adopted and implemented by caregivers, these limitations act as barriers causing a slowdown in the rate of adoption. Designers of the innovation add technological capabilities aimed at making the innovation of broader use—yet these same capabilities detract from the ease of use by the caregiver, and increase the length and the complexity of the training of users [39].

The line of demarcation between the technology and the human user is not well established in such medical devices. As the technology evolves and becomes more sophisticated, caregivers abrogate to the device dimensions of the treatment which were previously a clinician-to-patient contact. This change in the role that the device plays in the clinical encounter tends to generate behavioral impediments to the diffusion of the medical device [35].

B. Behavioral and Human-barriers

Patients, especially the elderly [91]-[93], are impacted by the migration from personal to robotic contact during their clinical encounter with a caregiver. The move to the impersonal

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increases the dislike of these patients to feel controlled by a technological device. Caregivers are averse to the constant innovations in the technology which require learning new solutions and new characteristics and capabilities of the new versions of the device [94].

Resistance to change by caregivers is a common behavioral barrier found in the adoption of technological innovations [39], [89].

Any new device requires changes in work procedures and in the nature of the medical encounter. This requires caregivers to change their clinical behavior which they have mastered over many years of positive experience and expertise. No matter how effective the technology is, its newness and the need for learning and for personal adaptation to it, tend to exacerbate the natural instinct of humans in resisting change to change.

C. Organization barriers

The adoption of new medical technologies often requires a reorganization of activities and redistribution of responsibilities within the clinical organization. There are changes in the goals, interests and responsibilities among the stakeholders. The rehabilitation effort is a multi-disciplinary activity engaging several different organizational units. Robot-technology for rehabilitation will change the organizational balance of these units and disciplines, hence increasing the resistance to the adoption of the technology.

IV. ECONOMIC BARRIERS TO ROBOTICS TECHNOLOGY ADOPTION

There are several economic barriers to the adoption of robot technology in general and in rehabilitation in particular: adequate evaluation and cost-effectiveness techniques, reimbursement models, and other incentive mechanisms.

Robot-technology for rehabilitation requires high levels of investments and its maintenance and routine operation are relatively costly, depending on the type of rehabilitation. But this barrier (which is in line with the observed relationships between new technology and health care costs, as the case of robot assisted surgery [95]) may not be a significant impediment to long-term adoption, because it considers short-term costs of the technology.

To date, detailed and rigorous studies on the economic sustainability of robotic technologies for rehabilitation are very sporadic[1]. Wagner *et al.* [97] conclude their paper with a sentence that can summarize the problem: "However uncertainty remains about the cost-effectiveness of robotic-assisted rehabilitation compared with traditional rehabilitation" (Figure 4).

Since robot-assisted rehabilitation adoption is far from having reached significant levels, empirical studies are based on relatively small samples of patients, and the conclusions often are not very strong. This uncertainty on the economic implications of the robotic technologies in rehabilitation negatively affects payers' decision making process.

Moreover, hospitals, may also be reluctant in adopting the new technology. The reason is that, as robotic-assisted rehabilitation may reduce the number of hospitalizations (and all the related services), this could turn out to negatively impact the hospital reviews. In this case, we could have a situation in which the hospital may be less interested in introducing robotic-assisted rehabilitation than the final payer (e.g., insurance company, health national or local systems).

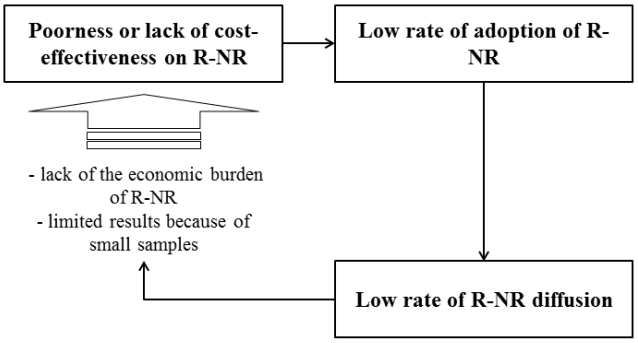

Figure 4. The cost effectiveness studies' poorness and R-NR technology low adoption rate vicious circle.

In addition, reimbursement regimes have a strong impact on new technology adoption [98].

Consider, for instance, the mechanism of diagnosis-related group (DRG) reimbursement. The main incentives of DRG-based hospital payment systems (reduction of costs per admission and/or increasing the number of adoption) go in an opposite direction with respect to a path of new technology adoption [99].

In case of a new technology increases costs per patient, while effectiveness being at least equal to the standard, the DRG system disincentives the adoption until the DRG is updated with the additional costs. The public and/or private healthcare systems must frequently modify the DRG-based mechanism to account for the development of new technologies in healthcare [100]. If this is not the case, in fact, the rate of adoption of new technology can be very low. Then, the rate of adoption of new technologies may also depend on the frequency and speed of the DRG system updating.

Therefore, in our opinion, the *scarcity of well-grounded studies on the economic and societal burden of robotic-assisted rehabilitation* that could take into consideration all the relevant dimensions of analysis is the most important barrier to a wider adoption of these technologies.

A. Why do economic barriers slow the rate of adoption of Robot-Mediated Neurorehabilation?

It is well-established that costs, cost-effectiveness calculations and reimbursement systems influence the adoption of technological innovations. Recent studies explored the reasons why proven technological innovations—sometimes superior to their competitors—yet fare poorly when commercialized [37]-[38], [85]. Famous cases include Ford's Edsel car, which was technological advanced, but failed in the marketplace, and Sony's Betamax, a smaller and superior device that failed in the marketplace in favor of the Video Cassette Recorder (VCR).

The cases in healthcare technology are more acute. In the case of new products with an innovative technology, the market consists of individual consumers whose preferences and affinities dictate the commercial success of the new

1 See [96] for a methodological introduction on assessing the societal and economic implication of technology innovation in rehabilitation.

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product. In the healthcare sector, we have a much more complex array of inter-connected consumers and users, with multiple influences upon the decision makers.

The complexity of the medical sector and healthcare organizations magnifies the economic barriers of marketability of technological innovations. The key issue is that the medical device may have a proven technology, often even superior to existing technologies, yet the market is slow in accepting it and in diffusing its widespread adoption. This may be explained by the fact that the economic evaluation of such devices cannot adequately produce satisfactory measures of value created by the device for users, patients, and other healthcare constituencies [101].

Economic value is a multi-faceted concept. In the case of the individual consumer of cars or recording devices, the value is embedded in the perception of the consumer that the product will provide certain value upon purchasing it. In the medical sector, these perceptions are distributed among the various constituents and each of them may require a different type of economic value.

The value accrued to users may be: return on investment (ROI); cost effectiveness; cost savings by switching to the new technology; improved regulatory compliance; and economic contribution to the user's goals and objectives. But, the question remains: to whom will any of the economic or financial benefits be important enough to warrant support for adoption and implementation of the technology? Hospitals have their own objectives and perceived value they require of the new device. These may not be the same as those of insurers and other payers, nor those of regulators and patients. Did the new technology reduce the cost of a clinical procedure, as compared with the existing technology? What type of value does each constituent considers in its decision to support adoption?

Finally, the measurement of value is also a barrier to adoption. There are different approaches to determining, for example, the savings accrued from the use of the new technology. Lower expenses may occur in the purchase of the new device but the costs may sharply rise when one computes the operational and replacement costs. There is a long way to go to reach agreement among the various players in the healthcare system regarding the nature and measures of the value they desire and actually obtain from the adoption of new technological devices.

The lack of strong studies on the economic burden of robot-technology for rehabilitation, the related uncertainty on the adoption of the technology that impacts on the previsions on the future revenue of the projects, the presence of very high hidden costs (e.g., service contracts, test equipment, deprecation, installation, licenses) that characterize the implementation of medical devices, disincentive the actual industrialization of robot-technology for rehabilitation [102]-[103].

Robot-technological solutions for rehabilitation often remain at a feasibility study stage where effectiveness is probably more important than the economic sustainability (also because effectiveness is less difficult to prove than the economic efficiency and sustainability of the designed solution in the short, medium, and long term).

The allocation of the resources for running feasibility studies often privileges the costs for buying the technology rather than involving a sufficient number of people and health institutions for testing the cost-effectiveness of the solution. At this level, the number of potential final users involved is often not sufficient for the methodological and statistical standards requested for conducting a cost-effectiveness study, or, at best, only one perspective is considered in the analysis, although users, payers, decision makers may strongly differ in their goals and interests.

V. Conclusions

The article highlights and discusses the limits of the adoption of robotic technologies for upper-limb rehabilitation. One limitation of the current study derives from the lack of more quantitative data on the market; thus, the contribution of this work is more intended to give qualitative, still useful indications on how to foster the adoption of robotic technologies for upper-limb rehabilitation. In other terms, the present article should be considered as a framework from and within which future research actions aiming at overcoming the barriers to the adoption of robotic technologies can be carried out.

Technological and behavioral barriers play a very important role in limiting a wider adoption of these technologies.

Robot-assisted rehabilitation could suffer for the fact that it could relegate patients on a passive role, not encouraging patients' self-improvement.

A more effective monitoring of the activities can overcome this limit. Rehabilitative technology that does not incorporate a monitoring (also remote) of patients' activities and actions, shows limits to adoption.

Technology should not substitute patient's effort or reduce his/her active role in the rehabilitation process [104]: robot, mental images, virtual therapies are useful for neuro-rehabilitation but they are not better than traditional rehabilitation [105].

For this reason, robot-technology should be considered a platform of *complementary* services that can enhance and improve the effectiveness and the efficiency (reducing time and health resources) of the rehabilitation process.

In addition, the vicious circle in which the adoption of this technology is locked in should induce researchers, public institutions and technology providers to invest in assessing the economic and societal burden of robotic-assisted rehabilitation, and to compare it with actual alternative solutions. Moreover, a more in depth analysis of the impact that the organizational and economic implications of a new technology and the related reimbursement mechanisms may produce on the incentive schemes of the adopters and the payers of the new technology should be performed.

A new technology, the new service models it generates, and its reimbursement level, in fact, modify the incentives of the different actors and then their behavior in favoring or limiting the adoption of a new technology.

In the process through which robotic technology for R-NR has been designed, developed and offered in the market, the importance of dissemination [25] for selecting the right

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channels for meeting the target audience and increasing the probability of technology adoption has been underestimated.

Therefore, a broader perspective of analysis, including the economical one, should be associated to the technological and clinical ones in the definition of the conditions for the adequate adoption of a new biomedical technology.

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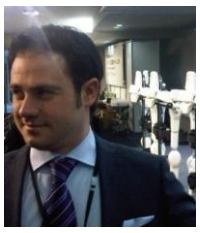

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