

E-HEALTH & TECHNOLOGIES:

new cultural and operational tools for health and rehabilitation practitioners











Rehabilitation is growing in Europe: ESPRM and its role

Attachments:

- Slide BTS
- Attachment 1 UEMS Position Paper
- Attachment 2 La Riabilitazione con Robot

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First PRM steps in Europe:

The first European significant data is the International Physiotherapy Conference in Rome 13th-16th October 1907.

After, between 1925 and 1935, several text books on Physical Therapy were published in Italy and many other Countries. The development of therapy with physical methods constitutes the medical-scientific origin, connected to the previous history of Hydrotherapy and Thermal treatments which had already developed into a very important sector oriented towards the use of movement as an element of health and cure (from the traditions of the Roman era/epoch to the medical instructions of Napoleon's army and the Hapsburg Empire). In Italy and in German speaking countries authorities were appointed to deal with insurance for accidents in the work-place, which developed into a growing activity in functional recuperation and prosthesis. The terms used are Physiotherapy and later Physical Medicine, then in the 1950s the terms Recovery and Rehabilitation also start to be used. The areas of clinical application have become more and more numerous, but in particular the activity is aimed at: the rehabilitation of disabled children, rehabilitation following traumatic lesions and injuries, rehabilitation following peripheral and central neurological lesions.

Schools were opened for doctors and other professions such as massotherapists and physiotherapists. Often using USA professionals as teachers (for example in Italy for PT or OT).

The 1st Conference of Physical Medicine was held in Marseille in 1957, then in Milan in 1958.

In 1962 the UEMS (European Union of Medical Specialties) recognised Physical Medicine as an autonomous discipline under the name of PRM. A characterizing element of that period which was very rich in clinical experience and innovative intuition, was the development of some particular methodologies (Brunnstrom, Vojta, Bobath, Kabat, Salvini-Perfetti, Maigne).

In these years the first national Societies of physical medicine (Italy, France, Portugal, Belgium, Holland) and European Academy were formed: on 25th April 1963 in Brussels, with an officialising act by the Royal Belgian Bulletin, the European Federation of Physical Medicine and Rehabilitation was formed, which initially grouped together the 9 National Societies which were already present on the Continent.

Was founded in these years Europa Medicophysica as Official Journal of the ESPRM Federation to diffuse education, information and research: recently it was transformed in the European Journal of PRM Medicine to enlarge the same aims involving better and better all European Countries.

Large areas of research developed among the first were the treatment of scoliosis, the care and treatment of subjects with war amputations and work injuries, and the thousands of cases of poliomyelitis in the 1950s. Other important field was Spine Injury (after war and working traumas) in Germany, GB and in Italy: very often first initiatives started by Neurologists - Neurosurgeons and only after driven to Rehabilitation.

The development after this period was much more rapid and widespread over all of the countries (in Western Europe), supported by important Documents of their Governments as well as by the Council of Europe and then by the European Union. The European Federation, with the UEMS and the Academy published the 1st White Book in 1989. .

Very strong elements in this scientific and operational development have been:

- The contribution of the professions of "allied" health workers, in particular: nurses, orthopaedic technicians, physiotherapists, speech therapists and occupational therapists.
- The thrust and richness of the commitment and the proposals by disabled persons associations and their families who have been able to transform pain, damage and the risk of desperation into a clear request for services and treatment. Thus requiring the national and European Community to carry out their cultural as well as economic duties.
- The contribution of many institutes, religious and private foundations who have dedicated themselves to this sector, must not be forgotten.

A further common effort is on the international and world-wide level, with the technical organs of the WHO based in Geneva, it is more and more important (in particular in closer European Countries) to gain attention for the problems regarding disability and rehabilitation in the documentation at this level.

This has also meant that many instructions from the European Parliament have taken a positive interest in policies in favour of the safeguarding of the rights of disabled people: the "Recommendation 1185 (1992)- Rehabilitation Policy for the Disabled" was decisive, at the end of the Decade 1981-1992 for Disabled People, and more recently the official definitions of the European Union have arrived regarding the value and content (with a particular positive relevance on PRM) of the Medical Act and the Quality that must be guaranteed at each medical examination

Undoubtedly, since the 1970s, the ideas that were maturing within the WHO, the indications of the Council of Europe's Directives, the rich and long debate on the ICIDH, and more recently the international document on Community-Based Rehabilitation, and finally, the definition of the ICF, have given us powerful stimuli but also strong elements for clarifying the aims of our work.

The ICF has formalised for everyone a language and a way of thinking that were always ours in Rehabilitation; the research and the applications that are currently coming to fruition provide new elements for our growth in all fields, as is happening with the DAR Action Plan WHO 2005/2010 "A world for all".

PRM now claim to be qualified for the overall study of Functioning and Health of a Person (and of a Community), for research into those elements that characterize it and that can modify it in the Person and his relational context, and for the management of the multidisciplinary and multiprofessional collaboration necessary both in order to carry out this research and to perform the therapeutic interventions.

PRM task is to make this Functioning evolve to an optimal level, compatible with the potentials and aspirations of the Person, using some specific therapeutic strategies:

- treating impaired body structures and functions,
- overcoming obstacles arising from changes in body functions, limitations of activities and restriction to participation,
- preventing the onset of further disability and limitation in functioning.

PRM now in Europe:

We all realise the great changes that have taken place in our perception of health, the conditions necessary for subjective wellbeing and for what we define as "quality of life". Disorders, symptoms and phenomena that perhaps in the past were supported and considered inevitable are now no longer accepted and demands are rightly made for all treatments that can eliminate or alleviate such problems. This is causing an ever more rapid expansion in the duties and aims of Medicine, as the frontiers of the needs and requests of citizens enlarge. There is a parallel expansion in overall requests for services and performances, which are not limited only to the field of health care, but extend more generally to social policies. Of course, all this must be proportional to the real existence and potential of treatments, based on scientific evidence and not only on hopes and illusions.

Rehabilitation is the sector of Medicine that, more than any other, is in the centre of this transformation: demand is growing and there is a parallel growth in the scientific potential to modify disabilities that previously could not be treated with success.

The starting point of all rehabilitation activities and associated professional and organizational responsibilities is the right of the individual, in the face of whatever Participation imitation and/or Disability that alters even only transiently his autonomy, self-sufficiency and self-determination to receive a diagnostic evaluation, a prognosis and, if possible, a treatment suitable for the problem related to his overall bio-psycho-social situation; these must be understandable and controllable by everyone. Social Participation is a term that very well represents the Person's fulfilment of this set of activities and rights.

The individual's right is inextricably bound to the duty of society to guarantee every person all the instruments suitable for maintaining, for as long as possible and at as high a level as possible, personal autonomy in participation in social tasks. It is also society's duty to optimise and at the same time verify the appropriate use of the many available rehabilitative instruments with respect to parameters of efficacy, efficiency and sustainability.

All this is hinged on the care relationship, on the modalities and contents of this care, on the procedures and their clarity with respect to equally clear verification systems which can be understood and checked, first and foremost by the individual in care: this implies certain types of language, relationships, paper work and even legislation that facilitate the active involvement of the Person in the process of regaining a state of well-being, autonomy and participation.

It is equally obvious and important that all the problems of the economic sustainability of services, in proportion to the evidence of their efficacy and suitability, must be approached with complete clarity of information. Such information, first of all for the choices in the general context of the population and in parallel for individual cases, is an essential element for building active and conscious involvement in the process of rehabilitation of the Person, and of the community as far as is necessary.

The instruments available:

We know that demands for health, treatments, restoration of autonomy and personal self-sufficiency are burgeoning and are being made by an ever broader group of people who, for numerous and extremely varied reasons, have found their state of well-being compromised. Research and clinical knowledge in our discipline offer ever greater possibilities of meeting these demands, with intrinsic, retraining and compensatory treatment methodologies and with therapeutic procedures that incorporate musculo-skeletal, kinesiological, neuropsychological, motivational, and occupational resources and potentials, etc.

The central point is the <u>Individual Rehabilitation Plan</u> which collects and distils all the previously mentioned concepts, and concretely expresses the true epicentric status that the Person must hold in all stages and in all interventions. The Individual Rehabilitation Plan represents the possible pathway for reaching an optimal state of well-being, participation and health; it combines the skills and duties of the various members of the team (which is the indispensable unit for rehabilitation care) and the different treatment settings and structures in the different periods of this process. The Individual Rehabilitation Plan defines, recapitulates and verifies the entire content of this tangible pathway towards recovery of as much autonomy as possible; it must, above all, be experienced and agreed by the Person, but it must also be based on precise and validated scientific elements.

However, these needs of unity and globality in rehabilitation care are not only manifested at a clinical level by the bio-psycho-social methodology of synthesis (as indicated in the ICF) which overcomes the fragmentation of looking at

organs, apparatuses and cells, but are also manifested in parallel and with equal importance in the management plan for the shared "governance" of the therapeutic choices, together with the aims and resources of the whole community.

In fact, from a managerial aspect, it is very important that each Health System can have the necessary comprehensive management organization for the instruments and resources used, in relation to their expected aims and achieved goals; it is equally important, given the rapid changes in demographic and socio-economic situations, that every Welfare System can have instruments to make the necessary connection between these interventions and the related health care aspects.

These cohesive elements, both on an individual level and at a population level, must represent the meeting point between scientific evidence and epidemiological evidence: a plan of Indicators of Health in different countries (e.g. the European Community as a whole), a plan that could, therefore, represent a well-founded and transparent list of the priorities of possible interventions in relation to their efficacy and efficiency is undoubtedly a fundamental aim for us all.

From the point of view of health care there is a need for the diagnostic, prognostic and therapeutic evaluation to have a unifying capacity, collecting together all the different elements in order to best understand the way in which the different pathologies, biological, psychic, emotional, relational, and affective problems, the socio-cultural conditions and context can interfere with the Person's functions, potential and desire to recover and reconstruct <u>Activity</u> and Health.

This capacity needs appropriate skills and instruments, it needs to develop and face the test of congruous and specific research, it needs an appropriate

language, shared by all the (many) medico-social but also politicoadministrative sectors involved.

In parallel there is a pressing need in the field of Public Health to define methodologies and instruments for collecting the data that illustrate the panorama of the problems (priorities, emergencies, quantitative dimensions, preventive potentials ...) and, if feasible, also the requirements (organizational and financial) to make the interventions possible.

In brief, we must move from an epidemiology of disease to an *epidemiology of limitations in participation*, which is much more significant in terms of real impact.

The <u>World Health Organization Classification</u>, the **ICF**, is nowadays the best instrument, at both clinical and community levels, for reaching these objectives: it defines all the investigations in a single, unifying vista, supplies the synthetic and unifying language, and offers a uniform methodology of interpretation and representation for all the determinants of the Health status of a Person and of a population.

The European Union, embracing all its member Countries, provides the means for representing and collating all the data on the health of this great Community, in scientific, administrative, social policy, cultural, educational and occupational terms.

Our background:

Is Physical Medicine and Rehabilitation really able to respond to the enormous challenge?

We could say that "when the going gets tough, the tough get going"; as tasks become increasing difficult and complex, only those who have the appropriate educational and professional instruments can tackle them completely, can fulfil the controls and can develop their own role further through research and experience.

Physiatry is not a very old discipline but precisely for this reason it has vigorous roots. Its taproot - which as always in Medicine is part science, part research, a craftsman-like experience in the field, much inspection of human relationships with people and critical reflection - highlights the duality of the "Physical" component, meaning attention to the whole physical environmental context which interacts positively or negatively with the Person and his problems, and the "Rehabilitative" component, meaning the finalised aim of every intervention.

The two components of this duality combine ever better, strengthening each other in research and in clinical practice. Precisely in the current transformation of health care demands they are showing their maximum potential and their enormous intrinsic value.

A traditional medical intervention concentrates on a disease process, and perhaps also takes into consideration the context, but only as a factor influencing the disease process. In contrast the clinical and research attitude of Physiatry never separates disease processes from the individual as a whole and his active and passive relations with his surrounding context; indeed the

physiatric approach is based constantly on the awareness that the determining factor is precisely this relation and not the isolated biological conditions.

It has been proposed to use the term "ecological" to emphasize this essential characteristic of our way of establishing every therapeutic relation.

In a traditional medical intervention the evaluations and prognosis are based on an analytic separation of the single bio-pathological factors followed by their rational integration into an overall sum; in contrast, a primarily rehabilitative view leads to considering the whole (functional, emotional, motivational and behavioural) as the primum movements focusing the parameters for determining the modality, limits and aims of the care only on this. Since health status is the result of a complex and large number of different factors, the therapeutic pathway to reach the maximum possible levels of recovery and maintenance must be equally complex, synergic and multifactorial, despite the fact that sometimes the single pathological conditions have a serious and chronically progressive course, or even a dismal prognosis.

There are Physiatrists who have highlighted this aspect, stating that while Medicine works against diseases and their consequences, Physical Medicine and Rehabilitation works for the "Functioning" of people notwithstanding diseases and their consequences.

Undoubtedly, since the 1970s, the ideas that were maturing within the WHO, the indications of the Council of Europe's Directives, the debate on the ICIDH, and more recently the international document on Community-Based Rehabilitation, and finally, the definition of the ICF, have given us powerful stimuli but also strong elements for clarifying the aims of our work.

The ICF has formalised for everyone a language and a way of thinking that were always ours in Rehabilitation; the research and the applications that are

currently coming to fruition provide new elements for our growth in all fields, as is happening with the DAR Action Plan WHO 2005/2010 "A world for all".

We can, I believe, now claim to be qualified for the overall study of Functioning and Health of a Person (and of a Community), for research into those elements that characterize it and that can modify it in the Person and his relational context, and for the management of the multidisciplinary and multiprofessional collaboration necessary both in order to carry out this research and to perform the therapeutic interventions.

Our task is to make this Functioning evolve to an optimal level, compatible with the potentials and aspirations of the Person, using some specific therapeutic strategies:

treating impaired body structures and functions,

overcoming obstacles arising from changes in body functions, limitations of activities and restriction to participation,

preventing the onset of further disability and limitation in functioning .

Rehabilitation is therefore a continuous process, carried out with problem solving methodology, centred on the relationship between a Person and his context: it incorporates and uses numerous methodologies, also of educational and pedagogic value, with simultaneous aims of prevention, treatment and maintenance. It is a process which is applied from the acute explosion of the problems (acute in a biological sense, but equally relevant for us, acute in terms of function and Functioning) but continues with equal intensity and importance in the subsequent stages of care.

This continuous process necessitates a multiplicity of skills from different sectors that might be called upon and it necessitates a multiplicity of structures and services to co-opt (over time and in different sites) which are not only strictly confined to the field of health care. If it is not to be complete waste of

time, it is a process that must be carried out, right from the start, with the active involvement of the Person and his individual and family entourage, because their roles are increasingly important, even in the strictly assessment and therapeutic stages.

Finally, it is a process that needs a strong cohesive guide, for two different but important reasons:

first of all to summarise both the information and the responsibilities in relation to the Person in care, but also in relation to all the other subjects involved (who pays, who participates as a worker, etc.)

and also to make a summary (in terms of efficacy of results and efficiency of the processes followed) of the performance of such a complex (and ever more expensive) series of interventions in a way that is clear and can always be verified.

Training in Physical Medicine and Rehabilitation, both nationally and internationally has improved rapidly thanks to the Universities, Scientific Societies, specialised journals and many congresses, and has been matched by an expansion of basic and clinical research: the standards guiding this improvement are precisely those described above and we now consider that we have full right to call ourselves, as some of our American colleagues have affirmed for some time, "physicians for the disabled".

PRM now is an independent medical specialty in all European Union, but its name and focus varies somewhat according to different national traditions and laws. Training usually lasts for between four and six years depending on the country (UEMS Charter on Training, EC Directive 93/16/EEC, 5 April 1993). Specialists in PRM have freedom of mobility across UEMS member states, but require certification from their national training authorities. (10,13).

The PRM specialist either performs the intervention aiming to solve the given problems or another team member may do so. In other settings the PRM-specialist will prescribe the therapy. Interventions include:

• Medical interventions

- o Medication aiming at restoration or improvement of body structures and/or function, e.g. pain therapy, inflammation therapy, regulation of muscle tone, improvement of cognition, improvement of physical performance, treatment of depression.
- o Practical procedures, including injections and other techniques of drug administration;
- o Assessment and review of interventions;
- o Prognostication.

Physical Treatments

- o Manual therapy techniques for reversible stiff joints and related soft tissue dysfunctions;
- o Kinesiotherapy and exercise therapy;
- o Electrotherapy;
- o Others including ultrasound, heat and cold applications, phototherapy (e.g. Laser therapy), hydrotherapy and balneotherapy, diathermy, massage therapy and lymph therapy (manual lymphatic drainage);
- Occupational therapy to a) analyze activities, such as those of daily living and occupation, support impaired body structures (e.g. splints), b) teach the patient skills to overcome barriers to activity of daily living (e.g. adjusting private facilities), c) train in the presence of impaired function and cognition and d) enhance motivation;
- Speech & language therapy within the framework of complex specialized rehabilitation programmes;

- Dysphagia management;
- Neuropsychological interventions;
- Psychological assessment and interventions, including counselling;
- Nutritional therapy;
- Disability equipment, assistive technology, prosthetics, orthotics, technical supports and aids;
- Patient education;
- Rehabilitation nursing.

Nowadays all these contents are really into the cultural basis and scientific knowledges, but not so clearly into practical and daily activity of every PRM Doctor in Europe: also the education curriculum in some Countries is not so common and commonly complete in every Countries.

Actual European socio-cultural panorama:

The present situation has been reached on a ethical, cultural and political level on the Continent, and therefore progressively also at the operational level (of research, offer of treatment and services etc.) in the Countries of the European Community, although with certain differences due in particular to different economical conditions.

In fact in every part of Europe the great changes that have taken place in the perception of health: the conditions necessary for subjective wellbeing and for what can be defined as "quality of life". Disorders, symptoms and phenomena perhaps in the past beard and considered inevitable, now are no longer accepted and demands are rightly made for all treatments that can eliminate or alleviate such problems. Rehabilitation is the sector of Medicine that, more than any other, is in the centre of this transformation: demand is growing and there is a parallel growth in the scientific potential to modify disabilities that previously could not be treated with success. As a consequence, the Physical and Rehabilitation Medicine and all its professionals have the proper social position and responsibility to communicate and understand all aspects in the Community, besides their daily clinical tasks of assisting individuals, solving their problems, showing feasibility and possibility to realize such goals. (16).

The starting point of all rehabilitation activities and associated professional and organizational responsibilities is the right of the individual, in the face of whatever Participation Limitation and/or Disability that alters even only transiently his autonomy, self-sufficiency and self-determination to receive a diagnostic evaluation, a prognosis and, if possible, a treatment suitable for the

problem related to his overall bio-psycho-social situation; these must be understandable and controllable by everyone. Social Participation is a term that very well represents the Person's fulfilment of this set of activities and rights.

The individual's right is inextricably bound to the duty of society to guarantee every person all the instruments suitable for maintaining, for as long as possible and at as high a level as possible, personal autonomy in participation in social tasks. It is also society's duty to optimise and at the same time verify the appropriate use of the many available rehabilitative instruments with respect to parameters of efficacy, efficiency and sustainability.

The World Health Organization Classification ICF, is nowadays the best instrument, at both clinical and community levels, for reaching these objectives: it defines all the investigations in a single, unifying vista, supplies the synthetic and unifying language, and offers a uniform methodology of interpretation and representation for all the determinants of the Health status of a Person and of a population. The European Union, embracing all its member Countries, provides the means for representing and collating all the data on the health of this great Community, in scientific, administrative, social policy, cultural, educational and occupational terms.

A role for ESPRM

The European Society of PRM was founded in 2003 and is concerned with research and teaching in PRM in Europe. It succeeded the European Federation of Physical Medicine and Rehabilitation (established in 1963) and aims to coordinate European activities and be a vehicle for scientific exchange. ESPRM maintains the particular scientific cooperation with European PRM Journal as previous Europa Medicophysica, and is working to endorse other Journals in different Countries (as France and Germany). The society offers individual membership to all eligible PRM specialists and federated membership members of the national PRM societies in Europe. Individual membership is free of charge. The ESPRM have an interactive electronic platform (www.esprm.org) and a periodical Newsletter to reach every PRM Specialist in the Continent , where information can be found on research projects, on grants and funding and offers updated information about courses, congresses, exchange funding, etc.

ESPRM organizes biennial scientific congresses in the field. The main topics were:

•Clinical Standards, Measurement of Outcomes and Effective Interventions in Neurological Rehabilitation, Musculoskeletal Rehabilitation and Amputee Rehabilitation. Advances in PMR – Traditional and Modern Concepts. Evidence Based Rehabilitation, Physical and Rehabilitation Medicine in lung transplant and in diabetes mellitus The scientific basis of PRM research. One of the most important Topics for Congresses, education activities and research projects in the recent period is surely the development of advanced and robotic technologies to improve and expand PRM interventions for any kind of

Health conditions. In this way ESPRM created a Special Scientific Interest Committee focused to cooperate and promote initiatives together other subjects and Professionals involved in these matters: mainly engineers and technical experts, producers of devices.

During all these years, was realized by ESPRM in a very close cooperation together other 2 European PRM Bodies:

UEMS PRM Section:

To promote the specialty in a professional capacity and to harmonise the specialty at a European level through specialist training and continuing professional development through revalidation. It works to develop clinical standards in practice and to facilitate the specialty to undertake the required research to develop it further. To this end, it is account-able (as with other specialties) to the UEMS and has started to work closely now with the European Commission and the Council of Europe. It has three main committees under an Executive Committee.

- Training and Education Committee (a statutory committee the European Board of PRM)
- Clinical Affairs Committee
- Professional Practice Committee

Académie Européenne de Médecine de Réadaptation — European PRM Academy.

This body of up to 50 senior doctors in the specialty across Europe was created in 1969. Academicians are invited on the basis of their distinguished contribution to the specialty, particularly its humanitarian aspects. The aim of the Académie is to improve all areas of rehabilitation for the benefit of those who need it.

Perspectives for this Role

So in the recent years are evident and urgent some problems (as previous presented):

- The Community in Europe, the People (disabled and not) needs a real and larger rehabilitation presence in health activities , but also in policy and cultural contents (also to cooperate in the evolution for the social security, for the quality of Life , quality of Living and quality of environment for all ages and conditions).

PRM can be ready to receive and to carry out this role at European level, and in each Country at the same time.

In brief, ESPRM scenario is the construction of a common European Health System, promoting visibility and awareness on the importance of Rehabilitation aspects, promoting adequate priority for these points in policy, in financial decisions. Promoting large consensus towards these concepts not only in medical world, but firstly in Disabled People Associations, in cultural, ethical political associations all over the European Continent . Trying to involve common communication means and general educational programmes .

The European Health System must move its basis from an epidemiology of disease to an epidemiology of (ICF) limitations in participation, which is much more significant in terms of real impact on Outcome focus, quality of life and managing aspects.

[&]quot;Robotics and new technologies:
great perspectives for Rehabilitation developments"

Forewords:

The growth in practices of Rehabilitation, in all of its field, applications and settings, is showing increasingly strong interaction with the growth, in all fields, of the potential of technology and its innovative applications.

Nevertheless, is should be stressed that the use of machinery has always been a fundamental mainstay of Rehabilitation practices (Physical and Rehabilitation Medicine, involving the whole physical world around the disabled people as it is): as it was in the past with physical exercises, physical modalities, and in many other activities that employed physical and technological means as Aids, Prostheses and Orthotics.

Actually many new possibilities day by day offered by technologies support a continuous development for these traditional tools for rehabilitation, a continuous enlargement for their applications toward the better recovery of functioning and health for any subject with disability.

Today, on the other hand, the peculiarity of new technological equipment and methodologies for evaluation, but mainly for treatments in particular, is interacting actively and profoundly with rehabilitation practices, very often subverting many previously shared theoretical, clinical and management paradigms.

So many different applications (new and not only) of technologies are fundamental in therapeutic interventions and in Activity /Functioning recovery .

What is robotic and what assistive (new) technology?

A large difficulty arises from a, not well defined at the moment, classification of the types and categories of these devices and apparatus regarding the so many differences in characteristics, utilization, aims etc. .

There is until now no complete consensus on which machines can be qualified as Robots but there is general agreement among experts, and the public, that robots tend to do some or all of the following: move around, operate a mechanical limb, sense and manipulate their environment, and exhibit intelligent behaviour, especially behaviour which mimics humans or other animals.

It can summarized as follows: Robots have actuators and sensors, the action they are performing is based on the sensed status or environment and there is an intelligent reaction to this status or environment. Without the intelligence it is "only" an automat.

Rehabilitation robotics is a special branch of robotics, which focuses on machines that can be used to help people recover from severe physical trauma. The born of this speciality is unclear but the first clinical robot application can be in the 1960s with Powered Human Exoskeleton Devices. Its context has varied between tools for delivering repetitive training; to tools to influence relearning lost motor skills in an engaging and therapeutic context. Numerous robotic devices for recovery lower or upper limb or hand function with various levels of complexity and functionality have been developed over the last 10 years. In clinical practice a robotic device for rehabilitation was define as any technology that has the ability to assist the patient's limb movement for therapeutic exercises and able to support the therapist during administration of programmable and customized rehabilitation programs, composed by mechanical structure with actuators and energy supply.

Two main approaches have been used to design upper and lower limb rehabilitation devices: end-effector and exoskeleton with or without a haptic system control.

On the other hand Assistive Technology is defined as "any item, piece of equipment, or product system whether acquired commercially off the shelf, modified or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities. It is a broad range of devices, services, strategies, and practices that are conceived and applied to ameliorate the problems faced by individuals who have disabilities."

AT devices are tools for enhancing the independent functioning of people who have impairments or disabilities. They range from low-tech aids, such as built-up handles on eating utensils, to high tech devices such as computerised communication systems, alternative access systems or powered wheelchairs. The ultimate objective of AT is to contribute to the effective enhancement of the lives of people with disabilities and elderly people by helping to overcome and solve their functional problems, reducing dependence on others and contributing to the integration into their families and society.

It is not so easy to define exactly the kind of some devices: for example a wearable exoskeleton (whit sensors and actuators, intelligent reactions for the training and for the independent standing /walking) belongs to robot or only to new assistive technology?

Only a point is easy to understand: as it is useful to enrich and motivate the training and to upgrade the results!

These definitions have several important elements. Both emphasise the functional capabilities of individuals with disabilities as a result of the successful use of these different devices and take a strong perspective on the outcomes in terms of quality of life. It underscores the importance of assessing and supporting the unique needs of each individual and the context in which they will be applying the devices .

Nevertheless, it is growing other different kinds (Virtual Reality and Tele-rehabilitation) of new applications of technology in rehabilitation :this development is a natural consequence of the rapid expansion of electronics and communication technology, providing new possibilities for independent living for individuals with neurological and other disabilities.

It is really not so easy to combine these devices in relation to the previous 2 definitions: the only key-point could be "New technologies" and could be sufficient.

The application of tele-rehabilitation as an adjunct to traditional clinical service may offer major benefits, particularly in terms of improved communication and access to health care over distance. Improved communication allows information sharing or even medical data exchange between patients, family, carers, clinicians, and researchers. It also may be a stimulating factor for extending the dialogue between patients and carers or clinicians and as such may be a potential source of augmented feedback. Access to health care over distance offers people living in remote areas the possibility to access to health care services or allows access to health care in specialised facilities located at longer distance from the place where the patient is living . Other potential advantages of access to health care over distance are the possibility of early diagnosis and start of therapy in acute situations, improving continuity of (specialised) care with possibilities for shortening length of stay in hospital or specialised rehabilitation centre, continuous monitoring of people at risk, and therefore reducing travelling costs and time between home and health service centre.

Tele-rehabilitation appears to be often applied as an adjunct to virtual reality tools when these are used in the home environment. Virtual reality techniques and high speed networks create an environment allowing clinicians and technical staff at different sites to interact with 3-dimensional visualisation of patient-specific data . Popescu et al reported the development of a PC-based orthopaedic rehabilitation for use at home, while allowing remote monitoring through videoconferencing from the clinic. A library of virtual rehabilitation routines was developed, consisting of three physical therapy exercises (Digikey, ball, and power putty) and two functional rehabilitation exercises (peg board and ball game). Burdea et al reported on the application of the Rutgers & Stanford system for rehabilitation of hand, elbow, knee and ankle impairments on the basis of virtual reality, haptic interfaces and networked PC's to provide exercises while being monitored remotely by therapists.

In recent years many different systems was developed for training in virtual rehabilitation and often tele-rehabilitation (cognitive and speech problems, balance, upper and lower limbs ...) and their diffusion is well known. Not necessary diffusion as "Home Rehabilitation" but mainly as distance-rehabilitation, remaining in the Rehabilitation Centre to reduce costs for personnel and implement time for training.

To be able to face to these new aspects, showing how these are parts (really new but completely inner to the scientific and practical role of PRM) belongs to the our Discipline evolution, showing also if and how many other professionals and different technicians can cooperate under the guidance of PRM Doctors in the Team, with the common aim to enrich the scientific results and outcomes for Peoples in treatment, showing how any evaluation for research and for certifications regarding these new technologies and their clinical applications belongs to PRM :all that is today fundamental to support and expand PRM.

In Europe we are actually trying to define a common vision all around these problems, recognizing and understanding the main points regarding the

competences and activities of PRM Doctors; the tools are scientific aspects (really very little at now) but mainly our professional, clinical and management experiences and opinions about how Rehabilitation processes and facilities must be guided, about how education and research must be addressed, about how relationship with other professionals must be utilized.

Some critical remarks: Key-problems for PRM

This field takes concrete form, in particular, with projects and experiences for the use of innovative equipment and technological systems as supports, interaction or instruments for the realisation of various types of treatment, for different purposes.

This interaction discloses great positive aspects, but also strong critical points due to the objective difficulty in correlating the actual needs of rehabilitation practices with appropriate responses on the part of technological research, as well as with verification of the efficacy and efficiency of these innovations.

We all openly can see the growth and quick diffusion every were of these offers in a concrete "market" (involving science, hope and illusion) very often subverting rules of care for health: many Companies are strongly promoting these instruments more and more in our Countries, scientific literature shares interesting experiences in Europe and all over the world, commercial advertising is strongly present near (TV, newspapers etc.) people, families and disabled people Associations.

One of the most important criticisms in this "market" is that disabled people (his family and community) needs to can choose cares not only referring to the scientific/medical/traditional basis and standards but mainly referring to the "client satisfaction" that means "disabled satisfaction" regarding individual health, participation and quality of life.

Goals for Health Services are changing in all of our countries under the power of free choices done by people and patients: not only to reach recovery but more often to reach a time of well-being, having the possibility, longer as possible, to maintain the best level of Participation and Autonomy.

Rehabilitation can be the key-word, and the key-role!

So the strongest tool for us is to apply ICF in all its value: to guide information to patients, researches, measures, indications, results in patients(persons) life, evidences, efficacy/effectiveness (also regarding finances and fees).

ICF must be the cornerstone for our methodology in any activity, and firstly the cornerstone for our education re-directing and strengthening all our knowledges and competences.

All these arguments involve the whole PRM, but surely robotic and new-technologies have a special value in this development. For example:

- -are totally inside and promote these changes,
- -can offer more and more changes,
- -bring these new possibilities to care directly to the whole person (physical, cognitive, relational, environmental aspects) underlining his autonomous action.

But unfortunately, as in any relevant transformation, the change can assume a positive or negative direction: there are some critical aspects that our ethical, scientifical and professional duties must face.

Also in the awareness that only PRM can do it as needed by disabled people rights, and by needed sustainability of Health Services.

A) - Lack of complete clinical instructions -

The first and big critical point is often (and for many of the equipments on the market) that there are no specific clinical elements of rehabilitation evidence to support the proposals that companies introduce. Often there is only basic but simple kinesiological, static-mechanical or neuro-functional evidences; in other cases there are only cognitive, behavioural, sensor and relational elements, which are however entirely simple and elementary and are definitely not

correlated to overall processes of understanding, learning and functional acquisition for the recovery in functioning and participation.

Also the References, actually increasing more and more, don't yet offer evidences suitable for the many and different applications.

In this sense, there is a great need for overall rehabilitative verifications on existing equipment, as well as for rehabilitative research to better orient companies' technological applications in future (to modify the existing or to create new ones.

Moreover, some great positive perspectives (to be developed) also emerge:

- •first of all, the possibility to have new tools to study and clarify modalities of therapeutic interventions, of learning recovery and evidences in our clinical activities;
- •the possibility to guarantee great homogeneity and measurability of treatments, as well as of the relative effects and functional results;
 - •the possibility, therefore, to realise wide-ranging and significant clinical studies, to bring out evidence of a biomechanical and functional nature and on individual performance.

B) - Needs for new organization and for economical recognitions -

Other critical elements in this phase turn up in the field of management and organisation (in the facilities, in the individual rehabilitation project, in the PRM Medical prescriptions) to apply these instrument, but also to obtain the resources that this development requires.

As a matter of fact very often these new modalities for treatment have not a specific recognition, quite if it is the same of the other "traditional" way: one of the most important cause is the point A, but also the financial crisis in Health Services in any Country is important too.

Therefore arises limitations and differences among Rehabilitation Centres that can equip (or not) themselves with this innovative machinery, giving rise to doubts as to disparities in treatment among the many types of persons with disabilities to submit (productively?) to treatments.

Moreover, some great positive aspects (to be developed) also emerge:

• the possibility to implement tele-rehabilitation on a large scale, in its different forms, understood as an appropriate form of continuity and effectiveness of treatments, integrating them with the environment, individual and motivational lifestyles of Persons who are deeply and actively involved.

last but not least, a concrete possibility to multiply care in relation to the multiplication of demand on the part of persons with disabilities, without excessive conflict with the costs that the use of only personnel would produce.

C) - New Education -

Additional critical elements that emerge is the objective need to modify the contents of training for Rehabilitation Team personnel, for the appropriate and widespread use of technological equipment in rehabilitative treatment, as well as the organisation of various activities in the different temporal phases of treatment.

Also the relationship between the PRM and patients is modified with respect to the substantial aspects of accepting patients for care and therapy and conducting the treatment between the patient and operational personnel. The change for PRM is mainly in research and define new clinical paradigms, protocols and guidelines, adding to the previous knowledges.

The question now arises as to whether this equipment can, perhaps partially regarding some traditional activities, replace specific categories of operational personnel (Physiotherapists, Speech and Language Therapists, Occupational

Therapists); or perhaps substitute rehabilitative settings where therapeutic programmes are traditionally carried out (Tele-rehabilitation).

In analysing relations between operational personnel and equipment, the theme of "difficulty" in performing work is also posed, which tends to show up with Physiotherapists (etc.) and which is also one of the elements of adaptation for patients (for their hardships), in their progress in performing exercises.

The machinery, on the other hand, is not subject to these adaptations and we should imagine further "intelligent" evolution to enable it to adapt productively to reactions of persons undergoing therapy.

Another aspect (only a brief note but the point has a wide scientific contents fro the patients and for the professional too) is the "fatigue" in the training and in the single exercise, which modify the repetitions, the strength, the characters etc. Fatigue can underline or involve aspects regarding attention (not only by patient), participation , motivation.

Obviously the machine do not have fatigue! But could be necessary to adapt the activity programmes in the machinery to avoid problems connected with risks of fatigue for the patients during the training.

So the problem is precisely the specific (new) competence of operational personnel, who can survey and guarantee the exactness of these therapeutic procedures. Surely it is quite new regarding the traditional previous role for Professionals: realizing the treatment directly "by hands".

It needs a quite different new education for these professionals, a quite new role in the global management of the treatment programmes, times, measurements and responsibilities.

D) - Care relationship -

Actually, due to the effects of this equipment, the position and attitude of patients towards their programme of recovery and towards the proactive behaviour they must endeavour to implement in its realisation is very often substantially modified as well.

The primary need is therefore confirmed of global and individual care for the Person in the Individual Rehabilitation Project, in order to bring every intervention to a therapeutic and evaluation synthesis. This situation , much more complex , request a solid role for responsibility in the hands of PRM Doctor obviously regarding the prescriptions for technological treatments , evaluations of results, coordination with other interventions in the recovery program.

The equipment is sometimes included as a "support and multiplier" to extend activities and treatments at every level, maintaining a relation with the "traditional" care program regarding the different clinical situations. But the machine on the contrary for example can show results on time, can create a sort of "positive game" for the patients, and directly communicating to the patients, in such a way excluding the professionals.

Other times the equipment is introduced as an entirely new potential (which would otherwise not be possible) to perform rehabilitative training that must in any case be included in organic care programmes, under the guidance of the PRM physician and with the intervention of adequately prepared Operators.

So immediately, in both cases, the equipment creates a new situation in which the information, the involvement and communications about results must be up-graded toward patients, family and care-givers: it is better also regarding to the active role of the Person in care as necessary.

Obviously also this last point, as the previous, is strongly connected and based on the first point **A).**

According with these matters, PRM European Bodies defined a specific Position Paper to clarify and guide this developing field. (Annex 1)

References

- A coherent policy for people with disabilities. Recommendation R (92) 6. Council of Europe. Strasbourg. EU Council of Ministers Meeting, Malaga: European Union: 2003.
- -Delarque A, Franchignoni F, Giustini A, Lankhorst G. European Physical and Rehabilitation Medicine: 3 years after White Book. Eur J Phys Rehabil Med. 2010 Mar; 46(1):1-4.
- -Giustini A. From acute intervention to domiciliary and social integration: research to build Community-Based Rehabilitation (CBR) on effectiveness". International Journal of Rehabilitation Research v. 27 suppl. 1 June 2004 pag. 44-45.
- -Giustini A. "Certainties and prospects in PRM" . EuraMedicoPhys., v.41 Sept.2005,pp.215-219,.
- -Guidelines for rehabilitation service in Italy . Eura Medico Phys,Vol 41,n.1, 2005, pp.95-109.
- -Lo AC, Guarino PD, Richards LG, Haselkorn JK, Wittemberg GF, Federman DG et al. Robot-assisted therapy for long-term upper limb impairment after stroke. N Engl. J Med 2010; 362: 1772-83
- -Holden MK. Virtual environments for motor rehabilitation: review. 26.Cyberpsychol behav 2005; 8: 187–211.
- -Huijgen B., Vollenbroek-Hutten M., Zampolini M., Bernabeu M. Feasibility of home-based telerehabilitation system compared to usual care: arm/hand function in patients with stroke, traumatic brain injury and multiple sclerosis Journal of Telemedicine and Telecare- 14 2008, 5-20

- -Man DW, Soong WY, Tam SF, Hui-Chan CW. A randomized clinical trial study on the effectiveness of a tele-analogy-based problem-solving programme for people with acquired brain injury (ABI). NeuroRehabilitation 2006;21:205–17
- -Mehrholz J, Werner C, Kugler J, Pohl M. Electromechanical-assisted training for walking after stroke. Cochrane Database of Syst Rev 2007 (4): CD006185
- Mehrholz J et al. Electromechanical and robot-assisted arm training for improving arm function and activities of daily living after stroke. Cochrane Database of Syst Rev 2008 (4): CD006876
- -Piron L, Tonin P, Piccione F, Iaia V, Trivello e, Dam M. Virtual 17. environment training therapy for arm motor rehabilitation. Presence 2005; 6: 732–740.
- -Rehabilitation and integration of people with disabilities: policy and integration. Strasbourg: Council of Europe Publishing, 7th edition: 2003; p 369.
- -Reinkensmeyer DJ, Pang CT, Nessler JA, Painter CC. Web-based telerehabilitation for the upper extremity after stroke. IEEE Trans Neural Syst Rehabil Eng 2002;10:102–8
- -Sale P, Franceschini M, Waldner and Hesse S Use of the Robot Assisted Gait Therapy in rehabilitation of patients with stroke and spinal cord injury .Eur J Phys Rehabil Med 2012 1:Vol 48
- -SPREAD National Stroke Guidelines- National Health Service-Italy, 2001. www.sanita.it..
- -Stucki G, Grimby G. Applying the ICF in medicine. Journal Rehabilitation Medicine. 2004 Jul (44 Suppl): 5-6.
- Stucki G, Ewert T, Cieza A. Value and application of the ICF in rehabilitation medicine. Disability & Rehabilitation. 2002; 24 (17): 932-8.
- -United Nations. Convention on the rights of persons with disabilities (resolution 61/106). New York, NY: United Nations; 2007.

- -UEMS-PRM-Section: Definition of Physical and Rehabilitation Medicine. www.euro-prm.org. 2005.
- -Ustun B, Chatterji S, Kostanjsek N. Comments from WHO for the Journal of Rehabilitation Medicine Special Supplement on ICF Core Sets. Journal of Rehabilitation Medicine. 2004 Jul (44 Suppl): 7-8.
- -Von Groote PM, Giustini A, Bickenbach JE. Analysis and Implementation of a WHO Health Report. Methodological Concepts and Strategies. Am J Phys Med Rehabil. 2013.
- -Wade DT. Community rehabilitation, or rehabilitation in the community? Disability & Rehabilitation. 2003; 25 (15): 875-81.
- -White Book on Physical and Rehabilitation Medicine. European Academy of Rehabilitation Medicine, European Federation of Physical and Rehabilitation Medicine, European Union of Medical Specialists (Physical and Rehabilitation Medicine Section): Universidad Complutense de Madrid; 1989
- -White Book on Physical and Rehabilitation Medicine in Europe. EuraMedicoPhys,Vol 42,n.4 2006, pp.289-332.
- World Health Organization. World Report on Disability. Geneva: World Health Organization; 2011.

Some relevant papers about Robotic Rehabilitation:

- [1] <u>Hesse S</u>, <u>Schmidt H</u>, <u>Werner C</u>, <u>Bardeleben A</u>. Upper and lower extremity robotic devices for rehabilitation and for studying motor control. <u>Curr Opin Neurol</u>. 2003 Dec;16(6):705-10.
- [2] R. Colombo, F. Pisano, S. Micera, A. Mazzone, C. Delconte, M.C. Carrozza, et al. "Assessing mechanisms of recovery during robot-aided neurorehabilitation of the upper limb," Neurorehabilitation and Neural Repair, vol. 22, Feb. 2008, pagg. 50-63.
- [3] <u>Kwakkel G</u>, <u>Kollen BJ</u>, <u>Krebs HI</u>. Effects of robot-assisted therapy on upper limb recovery after stroke: a systematic review. <u>Neurorehabil Neural Repair.</u> 2008 Mar-Apr;22(2):111-21.
- [4] R. J. Nudo, "Adaptive plasticity in motor cortex: implications for rehabilitation after brain injury," J Rehabil Med, 41 Suppl, pp. 7-10, May 2003.
- [5] M. Lotze, C. Braun, N. Birbaumer, S. Anders and L. G. Cohen, "Motor learning elicited by voluntary drive," Brain, vol. 126, no. 4, pp. 866-72, Apr 2003.
- [6] Prange GB, Jannink MJ, Groothuis-Oudshoorn CG, Hermens HJ, Ijzerman MJ. <u>Systematic review of the effect of robot-aided therapy on recovery of the hemiparetic arm after stroke.</u> J Rehabil Res Dev. 2006 Mar-Apr;43(2):171-84.
- [7] Mehrholz J, Platz T, Kugler J, Pohl M. <u>Electromechanical and robot-assisted arm training for improving arm function and activities of daily living after stroke.</u> Cochrane Database Syst Rev. 2008 Oct 8;(4).
- [8] <u>Oujamaa L</u>, <u>Relave I</u>, <u>Froger J</u>, <u>Mottet D</u>, <u>Pelissier JY</u>. Rehabilitation of arm function after stroke. Literature review. <u>Ann Phys Rehabil Med.</u> 2009 Apr;52(3):269-93.
- [9] Fazekas G, Horvath M, Troznai T, Toth A. Robot-mediated upper limb physiotherapy for patients with spastic hemiparesis: a preliminary study. J Rehabil Med. 2007 Sep;39(7):580-2.
- [10] C. Delconte, F. Pisano, M.A. Tommasi, A. Cavalli, D. Pianca, A. Mazzone, G Minuco, R. Colombo. La robotica in riabilitazione. G Ital Med Lav Erg 2009; 31:1, 115-123.
- [11] <u>Masiero S</u>, <u>Celia A</u>, <u>Rosati G</u>, <u>Armani M</u>. Robotic-assisted rehabilitation of the upper limb after acute stroke. Arch Phys Med Rehabil. 2007 Feb;88(2):142-9.
- [12] E.Carraro, S.Masiero, G. Rosati, C. Ferraro. Recupero della forza muscolare dopo precoce mobilizzazione passiva nel paziente emiplegico. Eur Med Phys 2008;44 (Suppl 1 to No.3)
- [13] Lum PS, Burgar CG, Van der Loos M, Shor PC, Majmumdar M, Yap R. MIME robotic device for upper-limb neurorehabilitation in subacute stroke subjects: a follow-up study. J Rehabil Res Dev. 2006;43:631-642.

- [14] Hesse S, Werner C, Pohl M, Rueckriem S, Mehrhoz J, Lingnau ML. Computerized arm training improves the motor control of the severely affected arm after stoke. Stroke. 2005;36:1960-1966.
- [15] Aisen ML, Krebs HI, Hogan N, McDowel F, Volpe BT. The effect of robot-assisted therapy and rehabilitative training on motor recovery following stroke. Arch Neurol. 1997;54:443-446.
- [16] Volpe BT, Krebs HI, Hogan N, Edelstein L, Diels C, Aisen ML. A novel approach to stroke rehabilitation: robot-aided sensorimotor stimulation. Neurology. 2000;54:1938-1944.
- [17] Rabadi M, Galgano M, Lynch D, Akerman M, Lesser M, Volpe B. <u>A pilot study of activity-based therapy in the arm motor recovery post stroke: a randomized controlled trial.</u> Clin Rehabil. 2008 Dec;22(12):1071-82
- [18] Krebs HI, Volpe BT, Aisen ML, Hogan N. Increasing productivity and quality of care: Robot-aided neuro-rehabilitation. J Rehabil Res Dev. 2000;37(6):639–52.
- [19] Hesse S, Werner C, Pohl M, Mehrholz J, Puzich U, Krebs HI. Mechanical arm trainer for the treatment of the severely affected arm after a stroke: a single-blinded randomized trial in two centers. Am J Phys Med Rehabil. 2008 Oct;87(10):779-88.
- [20] <u>Lin KC</u>, <u>Chen YA</u>, <u>Chen CL</u>, <u>Wu CY</u>, <u>Chang YF</u>. The effects of bilateral arm training on motor control and
- functional performance in chronic stroke: a randomized controlled study. <u>Neurorehabil Neural</u> <u>Repair.</u> 2010

Jan;24(1):42-51.

- [21] Takahashi CD, Der-Yeghiaian L, Le V, Motiwala RR, Cramer SC. Robot-based hand motor therapy after stroke. Brain. 2008 Feb;131(Pt 2):425-37.
- [22] Burgar CG, Lum PS, Shor PC, Van der Loos HFM. Developmentof robots for rehabilitation therapy: the Palo Alto VA/Stanford experience. J Rehabil Res Dev. 2000;37:663-673.
- [23] Lum PS, Burgar CG, Shor PC, Majmundar M, Van der Loos M. Robot-assisted movement training compared with conventional therapy techniques for the rehabilitation of upper-limb motor function after stroke. Arch. Phys Med Rehabil. 2002;83(7):952-959.
- [24] Volpe BT, Lynch D, Rykman-Berland A, Ferraro M, Galgano M, Hogan N, Krebs HI. <u>Intensive</u> sensorimotor arm training mediated by therapist or robot improves <u>hemiparesis in patients with chronic stroke</u>. Neurorehabil Neural Repair. 2008 May-Jun;22(3):305-10.
- [25] Amirabdollahian F, Loureiro R, Gradwell E, Collin C, Harwin W, Johnson G. <u>Multivariate</u> analysis of the Fugl-Meyer outcome measures assessing the effectiveness of GENTLE/S robot-mediated stroke therapy. J Neuroeng Rehabil. 2007 Feb 19;4:4.
- [26] Coote S, Murphy B, Harwin W, Stokes E. <u>The effect of the GENTLE/s robot-mediated therapy</u> system on arm function after stroke. Clin Rehabil. 2008 May;22(5):395-405.

- [27] Stefan Hesse, MD, Gotthard Schulte-Tigges, PhD, Matthias Konrad, MD, Anita Bardeleben, MA, Cordula Werner, MA. Robot-Assisted Arm Trainer for the Passive and Active Practice of Bilateral Forearm and Wrist Movements in Hemiparetic Subjects. Arch Phys Med Rehabil Vol 84, 2003; 915-921.
- [28] Fasoli SE, Krebs HI, Stein J, Frontera WR, Hughes R, Hogan N. Robotic therapy for chronic motor impairments after stroke: follow-up results. Arch Phys Med Rehabil. 2004;85:1106-1111.
- [29] Fasoli S.E., Krebs H.I., Stein J., Frontera W.R., Hogan N. <u>Effects of robotic therapy on motor impairment and recovery in chronic stroke</u> Archives of Physical Medicine and Rehabilitation 2003 84:4 (477-482).
- [30] Bovolenta F, Goldoni M, Clerici P, Agosti M, Franceschini M. Robot therapy for functional recovery of the upper limbs: a pilot study on patients after stroke. J Rehabil Med. 2009 Nov;41(12):971-5.
- [31] Kutner NG, Zhang R, Butler AJ, Wolf SL, Alberts JL. <u>Quality-of-life change associated with robotic-assisted therapy to improve hand motor function in patients with subacute stroke: a randomized clinical trial.</u> Phys Ther. 2010 Apr;90(4):493-504.
- [32] <u>Lo AC</u>, <u>Guarino PD</u>, <u>Richards LG</u>, <u>Haselkorn JK</u>, <u>Wittenberg GF</u>, <u>Federman DG</u>, et al. Robot-assisted therapy for long-term upper-limb impairment after stroke. <u>N Engl J Med.</u> 2010 May 13;362(19):1772-83. Epub 2010 Apr 16.
- [33] Ferraro M, Palazzolo JJ, Krol J, Krebs HI, Hogan N, Volpe BT. Robot-aided sensorimotor arm training improves outcome in patients with chronic stroke. Neurology 2003; 61(11):1604-7.
- [34] Staubli P, Nef T, Klamroth-Marganska V, Riener R. <u>Effects of intensive arm training with the rehabilitation robot ARMin II in chronic stroke patients: four single-cases.</u> J Neuroeng Rehabil. 2009 Dec 17;6:46.
- [35] Stein J, Krebs HI, Frontera WR, Fasoli SE, Hughes R, Hogan N. Comparison of two techniques of robot-aided upper limb exercise training after stroke. Am J Phys Med Rehabil. 2004;83(9):720-28.
- [36] Reinkensmeyer DJ, Kahn LE, Averbuch M, McKenna-Cole A, Schmit BD, Rymer WZ. Understanding and treating arm movement impairment after chronic brain injury: progress with the ARM guide. J Rehabil Res Dev. 2000;37(6):653-62.
- [37] Lum PS, Burgar CG, Shor PC. Evidence for improved muscle activation patterns after retraining of reaching movements with the MIME robotic system in subjects with post-stroke hemiparesis. IEEE Trans Neural Syst Rehabil Eng 2004;12(2):186-94.

- [38] R. Colombo, I. Sterpi, A. Mazzone, C. Delconte, G. Minuco, e F. Pisano, "Measuring changes of movement dynamics during robot-aided neurorehabilitation of stroke patients," IEEE Transactions on Neural Systems and Rehabilitation Engineering: A Publication of the IEEE Engineering in Medicine and Biology Society, vol. 18, Feb. 2010, pagg. 75-85.
- [39] Kahn LE, Averbuch M, Rymer WZ, Reinkensmeyer J. Comparison of robot-assisted reaching to free reaching in promoting recovery from chronic stroke. In: Mokhtari M, ed. Integration of Assistive Technology in the Information Age. Amsterdam, The Netherlands: IOS Press; 2001:39-44.
- [40] Kahn LE, Zygman ML, Rymer WZ, Reinkensmeyer D. J. Robotassisted reaching exercise promotes arm movement recovery in chronic hemiparetic stroke: a randomized controlled pilot study. Journal of NeuroEngineering and Rehabilitation. 2006;3;1-13.
- [41] Daly JJ, Hogan N, Perepezko EM, et al. Response to upper-limb robotics and functional neuromuscular stimulation following stroke. J Rehabil Res Dev. 2005;42(6):723-736.
- [42] <u>Housman SJ, Scott KM, Reinkensmeyer DJ</u>. A randomized controlled trial of gravity-supported, computer-enhanced arm exercise for individuals with severe hemiparesis. <u>Neurorehabil Neural Repair.</u> 2009 Jun;23(5):505-14.
- [43] <u>Hesse S</u>, <u>Mehrholz J</u>, <u>Werner C</u>. Robot-assisted upper and lower limb rehabilitation after stroke: walking and arm/hand function. <u>Dtsch Arztebl Int.</u> 2008 May;105(18):330-6.
- [44] Borggraefe I, Schaefer JS, Klaiber M, Dabrowski E, Ammann-Reiffer C, Knecht B, et al. <u>Robotic-assisted treadmill therapy improves walking and standing performance in children and adolescents with cerebral palsy.</u> Eur J Paediatr Neurol. 2010 Nov;14(6):496-502.
- [45] Farrell E, Naber E, Geigle P. <u>Description of a multifaceted rehabilitation program including overground gait training for a child with cerebral palsy: A case report.</u> Physiother Theory Pract. 2010 Jan;26(1):56-61.
- [46] Meyer-Heim A., Ammann-Reiffer C., Schmartz A., Schäfer J., Sennhauser F.H., Heinen F., et al. <u>Improvement of walking abilities after robotic-assisted locomotion training in children</u> with cerebral palsy. Archives of Disease in Childhood 2009 94:8 (615-620)
- [47] Borggraefe I, Kiwull L, Schaefer JS, Koerte I, Blaschek A, Meyer-Heim A, Heinen F. <u>Sustainability of motor performance after robotic-assisted treadmill therapy in children: an open, non-randomized baseline-treatment study.</u> Eur J Phys Rehabil Med. 2010 Jun;46(2):125-31.
- [48] Lo AC, Triche EW. Improving gait in multiple sclerosis using robot-assisted, body weight supported treadmill training. Neurorehabil Neural Repair. 2008 Nov-Dec;22(6):661-71.
- [49] Vaney C., Gattlen B., Hilfiker R. Effects of locomotion training with assistance of a robot-driven gait orthosis in patients with multiple sclerosis: a randomised controlled study. Abstracts Interlaken, 11.–13. Juni 2009.

- [50] Hesse S, Werner C, Bardeleben A. <u>Electromechanical gait training with functional electrical stimulation: case studies in spinal cord injury.</u> Spinal Cord. 2004 Jun;42(6):346-52.
- [51] Manella KJ, Torres J, Field-Fote EC. <u>Restoration of walking function in an individual with chronic complete</u> (AIS A) spinal cord injury. J Rehabil Med. 2010 Sep;42(8):795-8.
- [52] <u>Duschau-Wicke A</u>, <u>Caprez A</u>, <u>Riener R</u>. Patient-cooperative control increases active participation of individuals with SCI during robot-aided gait training. <u>J Neuroeng Rehabil</u>. 2010 Sep 10;7:43.
- [53] Swinnen E, Duerinck S, Baeyens JP, Meeusen R, Kerckhofs E. <u>Effectiveness of robot-assisted</u> gait training in persons with spinal cord injury: a systematic review. J Rehabil Med. 2010 Jun;42(6):520-6. Review.
- [54] Schwartz I, Sajin A, Fisher I, Neeb M, Shochina M, Katz-Leurer M, Meiner Z. The effectiveness of locomotor therapy using robotic-assisted gait training in subacute stroke patients: a randomized controlled trial. PM R. 2009 Jun;1(6):516-23.
- [55] Hidler J, Nichols D, Pelliccio M, Brady K, Campbell DD, Kahn JH, Hornby TG. <u>Multicenter randomized clinical trial evaluating the effectiveness of the Lokomat in subacute stroke.</u> Neurorehabil Neural Repair. 2009 Jan;23(1):5-13.
- [56] Mayr A, Kofler M, Quirbach E, Matzak H, Fröhlich K, Saltuari L. <u>Prospective, blinded, randomized crossover study of gait rehabilitation in stroke patients using the Lokomat gait orthosis.</u> Neurorehabil Neural Repair. 2007 Jul-Aug;21(4):307-14.
- [57] Husemann B, Müller F, Krewer C, Heller S, Koenig E. <u>Effects of locomotion training with assistance of a robot-driven gait orthosis in hemiparetic patients after stroke: a randomized controlled pilot study.</u> Stroke. 2007 Feb;38(2):349-54.
- [58] Ng MF, Tong RK, Li LS. A pilot study of randomized clinical controlled trial of gait training in subacute stroke patients with partial body-weight support electromechanical gait trainer and functional electrical stimulation: sixmonth follow-up. Stroke. 2008 Jan;39(1):154-60.
- [59] Pohl M, Werner C, Holzgraefe M, Kroczek G, Mehrholz J, Wingendorf I, et al. Repetitive locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial (DEutsche GAngtrainerStudie, DEGAS). Clin Rehabil. 2007 Jan;21(1):17-27.

- [60] Tong RK, Ng MF, Li LS. <u>Effectiveness of gait training using an electromechanical gait trainer, with and without functional electric stimulation, in subacute stroke:</u> a randomized controlled trial. Arch Phys Med Rehabil. 2006 Oct;87(10):1298-304.
- [61] Werner C, Von Frankenberg S, Treig T, Konrad M, Hesse S. <u>Treadmill training with partial body weight support and an electromechanical gait trainer for restoration of gait in subacute stroke patients: a randomized crossover study.</u> Stroke. 2002 Dec;33(12):2895-901.
- [62] M. Bragoni, G. Morone, L. Pratesi, P. Coiro, D. De Angelis, V. Venturiero, S. Paolucci. Effetto dell'utilizzo del gait trainer sugli outcomes riabilitativi nei pazienti con stroke in fase subacuta. EUR MED PHYS 2008;44(Suppl. 1 to No. 3).
- [63] Peurala SH, Airaksinen O, Huuskonen P, Jäkälä P, Juhakoski M, Sandell K, et al. Effects of intensive therapy using gait trainer or floor walking exercises early after stroke. J Rehabil Med. 2009 Feb;41(3):166-73.
- [64] Hesse S, Waldner A, Tomelleri C. <u>Innovative gait robot for the repetitive practice of floor walking and stair climbing up and down in stroke patients.</u> J Neuroeng Rehabil. 2010 Jun 28:7:30.
- [65] Freivogel S, Schmalohr D, Mehrholz J. <u>Improved walking ability and reduced therapeutic stress with an electromechanical gait device.</u> J Rehabil Med. 2009 Sep;41(9):734-9.
- [66] Hornby T.G., Campbell D.D., Kahn J.H., Demott T., Moore J.L., Roth H.R. <u>Enhanced gait-related improvements after therapist- versus robotic-assisted locomotor training in subjects with chronic stroke</u>: A randomized controlled study Stroke 2008 39:6 (1786-1792)
- [67] Michael D. Lewek, Theresa H. Cruz, Jennifer L. Moore, Heidi R. Roth, Yasin Y. Dhaher and T. George Hornby. Allowing Intralimb Kinematic Variability During Locomotor Training Poststroke Improves Kinematic Consistency: A Subgroup Analysis From a Randomized Clinical Trial. PHYS THER Vol. 89, No. 8, August 2009, pp. 829-839
- [68] Westlake KP, Patten C. <u>Pilot study of Lokomat versus manual-assisted treadmill training for locomotor recovery post-stroke.</u> J Neuroeng Rehabil. 2009 Jun 12;6:18
- [69] Dias D, Laíns J, Pereira A, Nunes R, Caldas J, Amaral C, et al. <u>Can we improve gait skills in chronic hemiplegics? A randomised control trial with gait trainer.</u> Eura Medicophys. 2007 Dec;43(4):499-504
- [70] Hesse S, Werner C, Uhlenbrock D, von Frankenberg S, Bardeleben A, Brandl-Hesse B. <u>An electromechanical gait trainer for restoration of gait in hemiparetic stroke patients: preliminary results.</u> Neurorehabil Neural Repair. 2001;15(1):39-50.

- [71] Peurala SH, Tarkka IM, Pitkänen K, Sivenius J. The effectiveness of body weight-supported gait training and floor walking in patients with chronic stroke. Arch Phys Med Rehabil. 2005 Aug;86(8):1557-64.
- [72] Moreh E, Meiner Z, Neeb M, Hiller N, Schwartz I. <u>Spinal decompression sickness presenting as partial Brown-Sequard syndrome and treated with robotic-assisted body-weight support treadmill training.</u> J Rehabil Med. 2009 Jan;41(1):88-9.
- [73] <u>Ustinova K</u>, <u>Chernikova L</u>, <u>Bilimenko A</u>, <u>Telenkov A</u>, <u>Epstein N</u>. Effect of robotic locomotor training in an individual with Parkinson's disease: a case report. <u>Disabil Rehabil Assist Technol.</u> 2010 Jul 28.

Tech-Reh project - Equipment for Uzbek laboratories



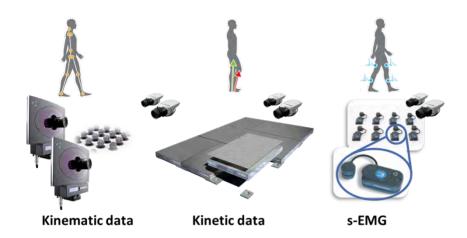


The human body can be considered a real «Sophisticated Machine» that we need to study.

We need «something» that help us to understand how human body is moving and working during the execution of any motor gesture, from the most basic to the most complex one.

GAIT LAB

BTS GAITLAB is a true integrated solution for the MULTIFACTORIAL analysis of walking, but also for any kind of movement, realized by 1 single PRODUCER



(slide reference GAIT LAB ppt.)

WEARABLE SYSTEM FOR THE FUNCTIONAL ANALYSIS OF MOVEMENT: G-WALK



The BTS G-WALK® gives important information to plan rehabilitation after injury or surgery, to maximize motor recovery trough an evaluation pre –post rehabilitation/intervention.

BTS G-WALK® can be used to monitor neurodegenerative diseases and disorders affecting the central nervous system that are causing atypical walking patterns.

In the field of prosthetics and orthopaedic devices customization, the BTS G-WALK® can be used in a wide range of applications allowing specialists to adapt their work to the patient characteristics in real time

(slide reference G-WALK ppt.)

ELECTROMYOGRAPHY DEVICE WITH WIRELESS PROBES FOR THE DYNAMIC ANALYSIS OF MUSCLE ACTIVITY: FREEEMG1000

Wireless Surface Electromyography (sEMG) Measures muscular activity during a dynamic movement



Wireless Surface Electromyography (sEMG) Measures muscular activity during a dynamic movement

From an sEMG recording the ON-OFF activity of a muscle can be identified.

(slide reference FREEEMG ppt.)

IMMERSIVE SYSTEM FOR MOTOR AND COGNITIVE NEUROREHABILITATION: NIRVANA



Speeds up and improves the rehabilitation process through the active involvement of the patient.

Patients of any age with motor and cognitive deficits of the lower and/or upper limbs, trunk resulting from:

- Brain injury (Post stroke, cranioencephalic traumas, brain tumours)
- Various forms of cerebral palsy (ICP)
- Neurodegenerative diseases (Parkinson's disease, multiple sclerosis, Alzheimer's disease)
- Developmental disorders,
- Disorders of memory and attention,
- Autism spectrum disorder.

(slide reference NIRVANA ppt.)

The Tech Reh Project



TECH_REH IS A EUROPEAN PROJECT FUNDED FOR TRAINING AND SUPPORT TO
THE CREATION OF A TECHNOLOGICALLY ADVANCED REHABILITATION SYSTEM IN
UZBEKISTAN.

BTS technology has played an important role as a tool to support a well-designed rehabilitation process.

The objective is therefore to train professional figures (doctors and physiotherapists) on innovative methods in the rehabilitation field.

Project objectives:

The general need of the clinician arises from the assumption that the biomechanical evaluation of a patient, in a static or moving position, is often of a qualitative type

This with to the consolidated methods for the acquisition of chemical and biological information for which, for some time, the Clinic has consolidated the need for quantitative information

The technological solutions for the research Project should be able to acquire the different biomechanical parameters of the subject, which are neuromuscular, kinematic, dynamic and cognitive parameters both integrated and in single mode, depending on the type of measurement.

To match the multifactorial parameters to an innovative rehabilitation program allows us to address and monitor the effectiveness of the rehabilitation choice.

The patient's treatment process:

- 1. Taking charge of the patient
- 2. Clinical history
- 3. Instrumental clinical evaluation
- 4. Understanding the level of functional deficit
- 5. Functional protocols for defining the best treatment
- 6. Rehabilitation treatment cycle (manual, robotic etc.)
- 7. The immersive reality NIRVANA is part of the normal rehabilitation process
- 8. Clinical evaluation and follow up
- 9. Final report of the patient

Training programme (19th August – 1th September)

August 19th

Arrival of the participants at Porto Potenza Picena

August 20th

- 9.30

Welcome at the Rehabilitation Hospital Istituto Santo Stefano - Conference Hall.

- 10.00

Work start:

Presentation of Internship Program and KOS Santo Stefano headquarters in Porto Potenza Picena (Alessandro Giustini - Massimo Vallasciani - Paolo Serafini - Enrico Brizioli).

Presentation of Participants.

- 12.30

Lunch at the canteen in the Hospital.

- 14.00

Work start:

Visit of the Institute.

Visit to the "Lampo" Movement and Posture Laboratory (Massimo Vallasciani and collaborators).

Presentation of the KOS Group.

Questions and answers.

- 17.30

Return of the Participants to the hotels.

August 21st

-9:30

Welcome at the Rehabilitation Hospital Istituto Santo Stefano - Conference Hall

-10:00

Work start:

Presentation of "Lampo" movement and posture laboratory - Role and perspectives of cooperation between engineers, doctors and health personnel in the evolution of rehabilitation activities and optimization of results for evaluation and treatment (Massimo Vallasciani and Lampo collaborators).

-12:30

Lunch at the canteen in the Hospital.

-14:00

Work start:

Visit and activities at the "Lampo" Laboratory.

State of Art, questions and criticisms from Uzbekistan participants.

-17:30

Return of the Participants to the hotels

August 22nd

-9.30

Welcome at the Rehabilitation Hospital Institute Santo Stefano - Conference Hall

-10.00

Work start:

Tech Reh Project-CT and Rehabilitation technologies.

State of art of rehabilitation technologies.

Needs of education and implementation in Rehabilitations (Alvydas Jocevicious - Denitza Slavova)

State of Art, questions and criticisms from Uzbekistan participants.

-12.30

Lunch

-14.00

Work start:

Upper limb treatments – (Gloreah)

Upper limb treatments (Diego)

Training with Participants.

State of Art, questions and criticisms from Uzbekistan participants.

-17.30

Return of the Participants to the hotels

August 23rd

-9.30

Welcome at the Rehabilitation Hospital Istituto Santo Stefano - Conference Hall

-10.00

Work start:

State of art of rehabilitation technologies.

Needs of education and implementation in Rehabilitations (Alvydas Jocevicious - Denitza Slavova).

-12.30

Lunch.

-14.00

Work start:

Upper limb treatments (Pablo).

Limb treatments (Amadeo).

Training with Participants.

State of Art, questions and criticisms from Uzbekistan participants.

-17.30

Return of the Participants to the hotels

August 24th

-9.30

Welcome at the Rehabilitation Hospital Istituto Santo Stefano - Conference Hall

-10.00

Work start:

e-Health, ICT and Telerehabilitation. Virtual reality (Alessandro Giustini - Alvydas Jocevicious - Denitza Slavova - Alberto Giattini - Paolo Serafini)

-12.30

Lunch.

-14.00

Work start:

Virtual Reality treatments - VRRS

Virtual Reality Training with participants.

Visit the smart home.

State of Art, questions and criticisms from Uzbekistan participants.

-17.30

Return of the Participants to the hotels.

August 25th

-9.30

Welcome at the Rehabilitation Hospital Istituto Santo Stefano - Conference Hall

-10.00

Work start:

Presentation of Rehabilitation in the NHS in Italy, of hospitalization and outpatient activities and of the role of technological activities (Alessandro Giustini - Antonello Morgantini - Massimo Vallasciani)

State of Art, questions and criticisms from Uzbekistan participants.

-12.30

Lunch

-14.00

Return of participants to the hotels.

August 26th

Free day

August 27th

-9.30

Welcome at Rehabilitation Hospital Istituto Santo Stefano Departure for MioLab Iesi (speaker TBD) Presentation and visit to MioLab.

-12.30

Lunch

-14.00

Start of work

The Visit continues.

Training with participants - Prokin and Walker -View platforms.

Paediatric water treatment

State of Art, questions and criticisms from Uzbekistan participants.

-17.30

Return of the Participants to the hotels

August 28th

-9.30

Welcome at the Rehabilitation Hospital Istituto Santo Stefano - Conference Hall

-10.00

Start of work

Basic and Modern Technologies in rehabilitation of musculoskeletal and some neurological disorders in Children. (Elena Ilieva - Denitza Slavova) Postural / motion technologies for evaluation and treatment (Hugo Silva - "Lampo" Laboratory)

-12.30

Lunch

-14.00

Start of work

Postural Treatments – (Hunova)

Training with participants

Training in the Lampo Laboratory.

State of Art, questions and criticisms from Uzbekistan participants.

-17.30

Return of the Participants to the hotels.

August 29th

BTS Training
The course wi

The course will be supported with practical tests:

FREEEMG1000 system

GWALK system

the NIRVANA system

-9.30

Welcome at Rehabilitation Hospital Istituto Santo Stefano - Conference Hall

-10.00

Start of work

INSTRUMENTAL EVALUATION (Massimo Vallasciani, Roberta Furone, Cristina Fiorucci, Mary Sargsyan)

The Movement Analysis Laboratory:

- 1. Optoelectronics kinematics
- 2. The triaxial force platforms
- 3. The stabilometric platform
- 4. Surface Electromyography
- 5. Inertial kinematics

-12.30

Lunch

-14.00

Start of work

Functional protocols and practical tests

- •I walk
- Time Up and Go
- Flex Relax
- Upper limb

-17.30

Return of the Participants to the hotels.

August 30th

BTS Training (Roberta Furone)

-9.30

Welcome at Rehabilitation Hospital Istituto Santo Stefano - Conference Hall

-10.00

Start of work

INSIGHTS ON SURFACE ELECTROMYOGRAPHY

- 1. Positioning of the electrodes
- 2. Interpretation of reports

NIRVANA

State of Art, questions and criticisms from Uzbekistan participants (Alessandro Giustini)

-17.00

Return of the Participants to the hotels.

August 31st

-9.30

Welcome at Rehabilitation Hospital Istituto Santo Stefano - Conference Hall

-10.00

Start of work (with a break at 11am)

Advanced technological equipment for the recovery of the functions lower limb and walking (Antonello Morgantini, Paolo Serafini)

-12.30

Lunch

-14.00

Start of work

Lower limb treatments (Geo System)

Limb treatments (Ekso)

Training with Participants

State of Art, questions and criticisms from Uzbekistan participants

-17.30

Return of the Participants to the hotels.

September 1st

-9.30

Welcome at Rehabilitation Hospital Istituto Santo Stefano - Conference Hall -10.00

Summary of the work of the Internship - Evaluation of the Teachers and Participants

Needs and perspectives for next professional development courses in Uzbekistan Universities .(Alvydas Jocevicious, Alessandro Giustini, Elena Ilieva)

-12.30

Lunch

-14.00

Closing remarks for the report in TechReh Project

-15.30

Return of the Participants to the hotels.





MOTION LAB

SURFACE EMG FUNCTIONAL PROTOCOLS



POSTURAL ANALYSIS

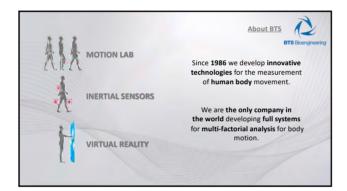
VIRTUAL REALITY SYSTEM FOR NEUROMOTOR REHABILITATION

SPORT TEST SYSTEMS

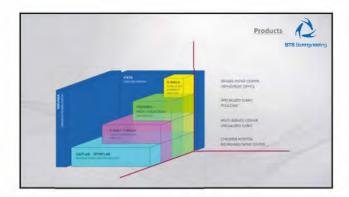
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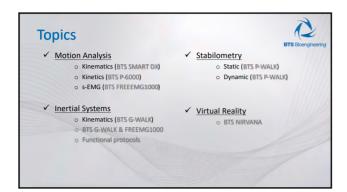








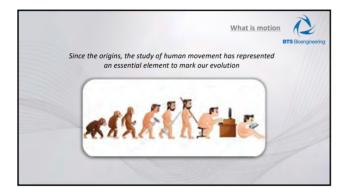


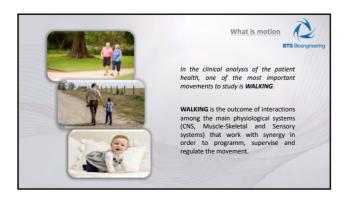


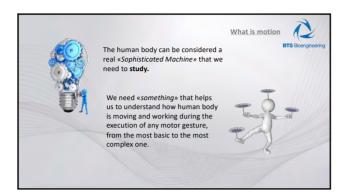




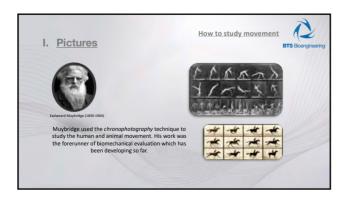




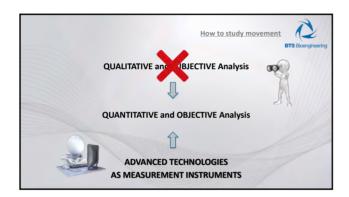




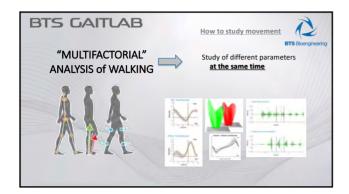


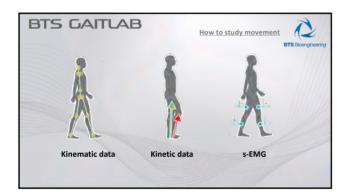


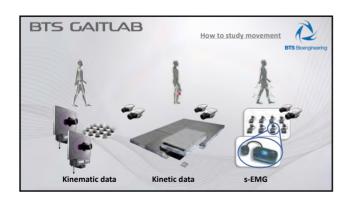




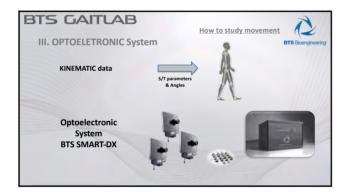


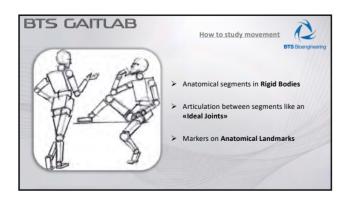


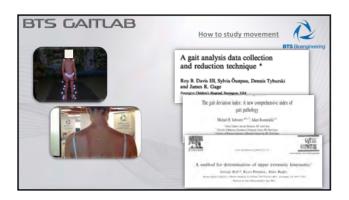


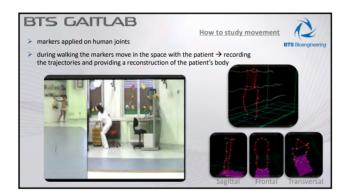


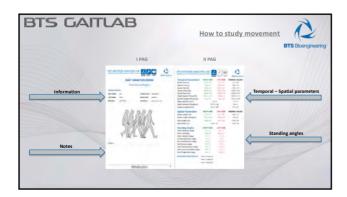


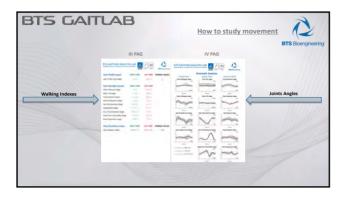


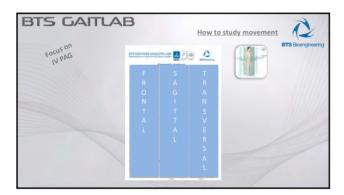




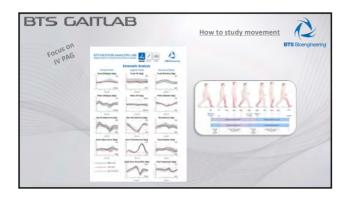


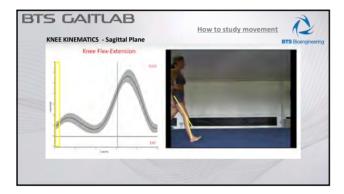


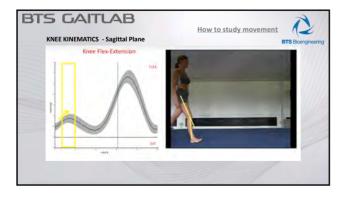


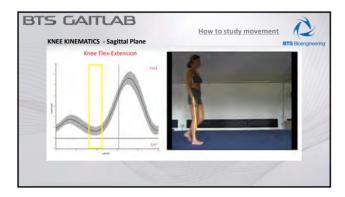


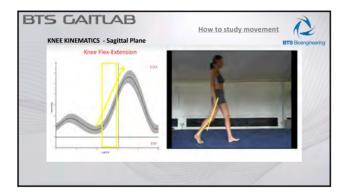


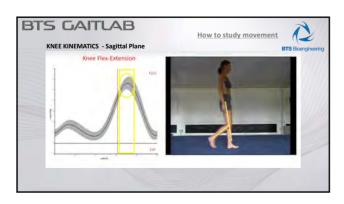


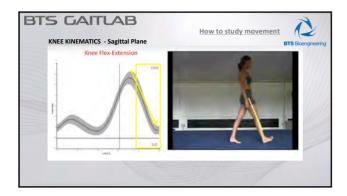




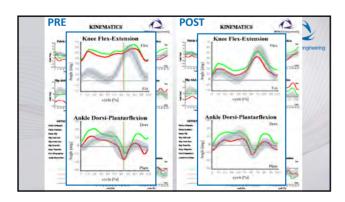


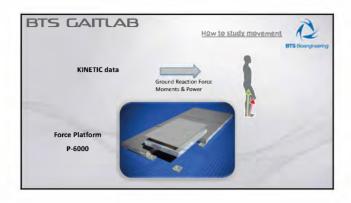


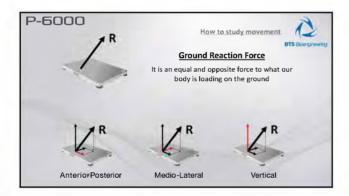






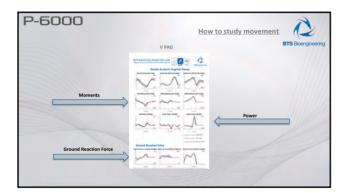


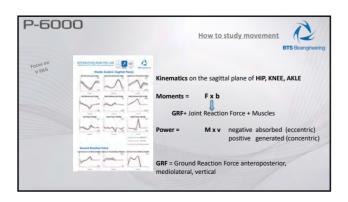




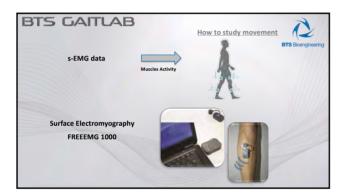


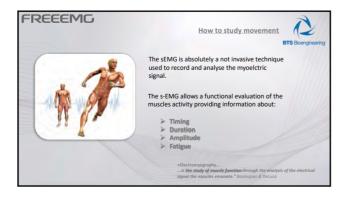


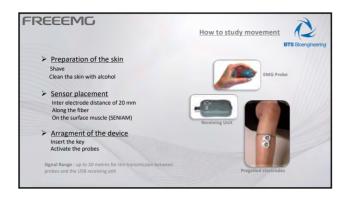


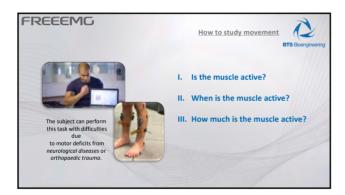


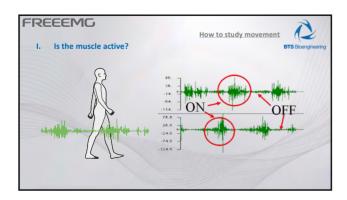


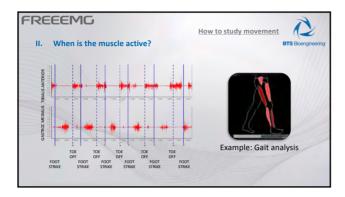


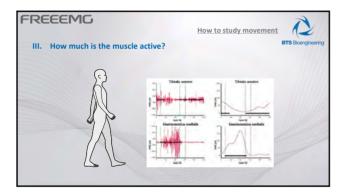


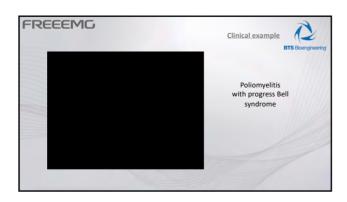




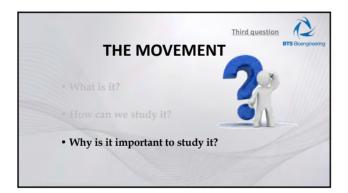




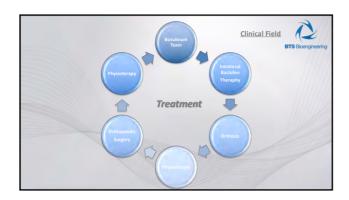


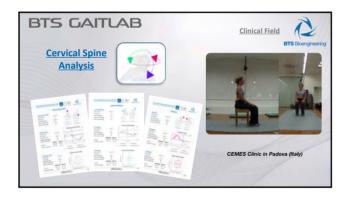


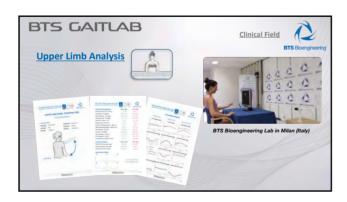


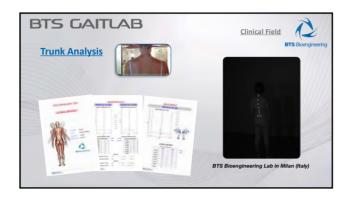


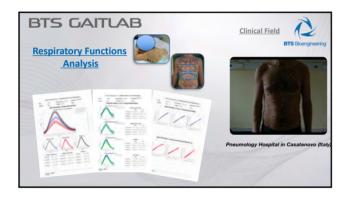




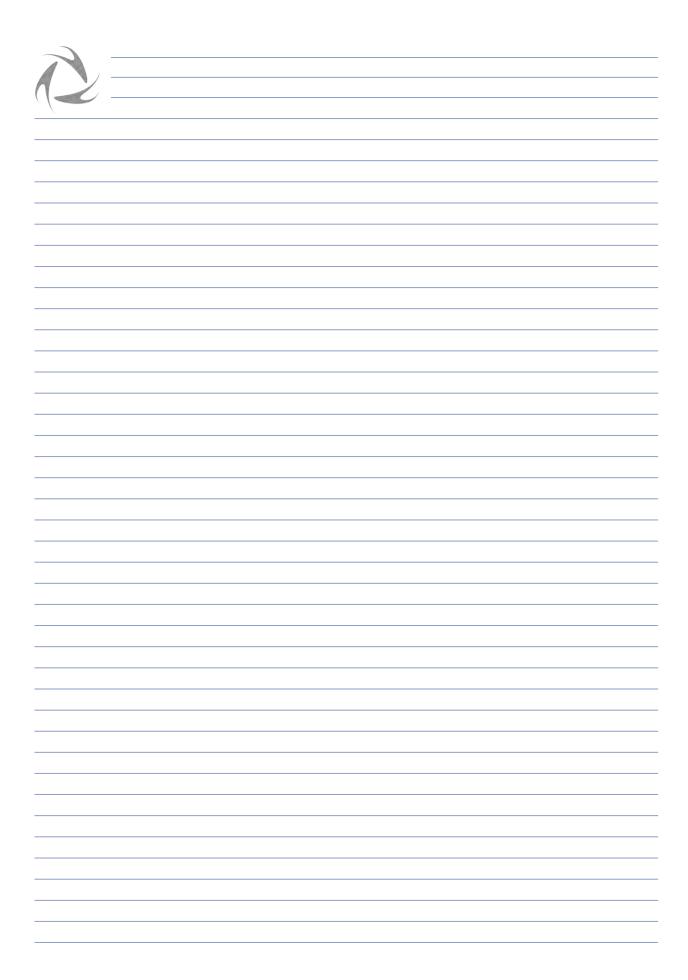


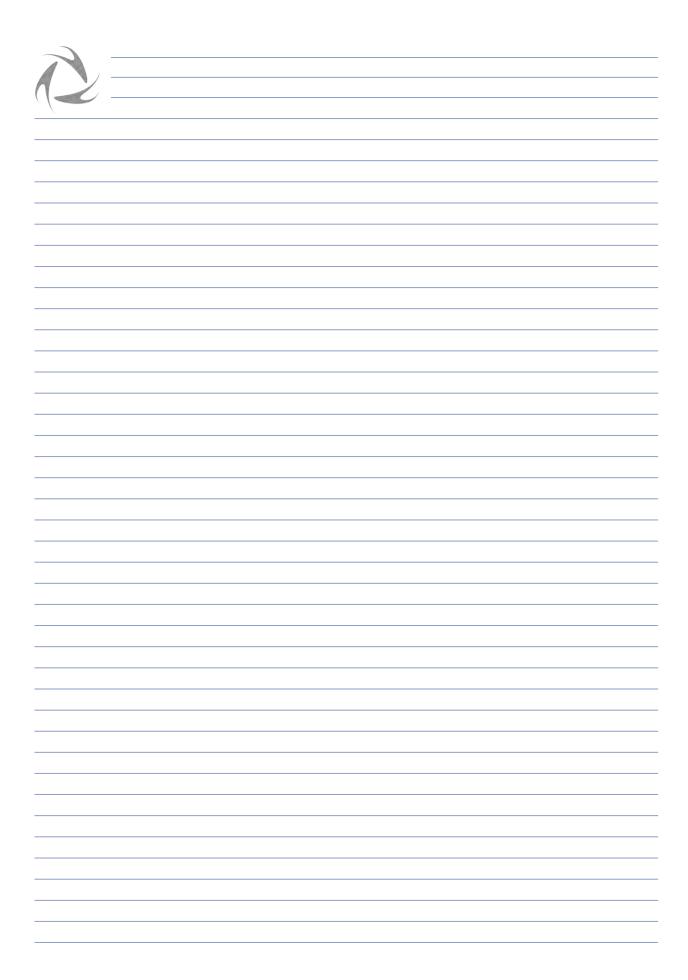
















MOTION LAB

SURFACE EMG FUNCTIONAL PROTOCOLS



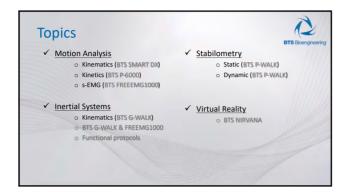
POSTURAL ANALYSIS

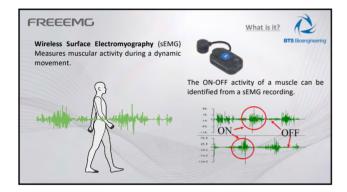
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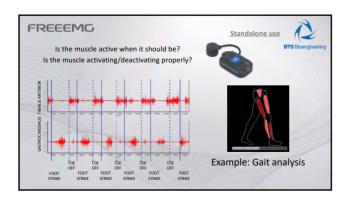
SPORT TEST SYSTEMS

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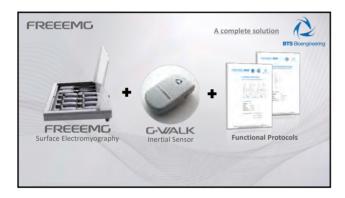






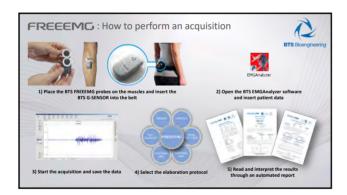


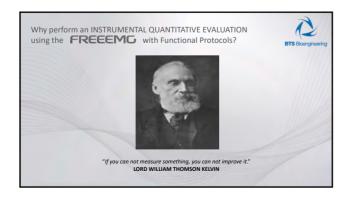


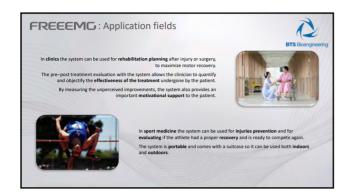


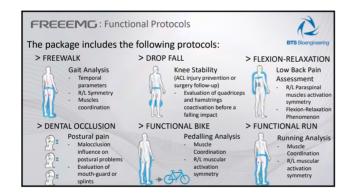


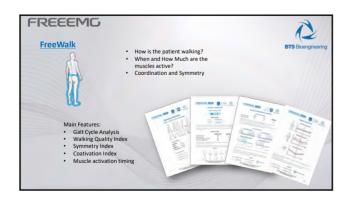










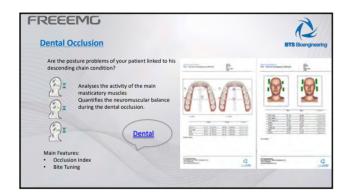




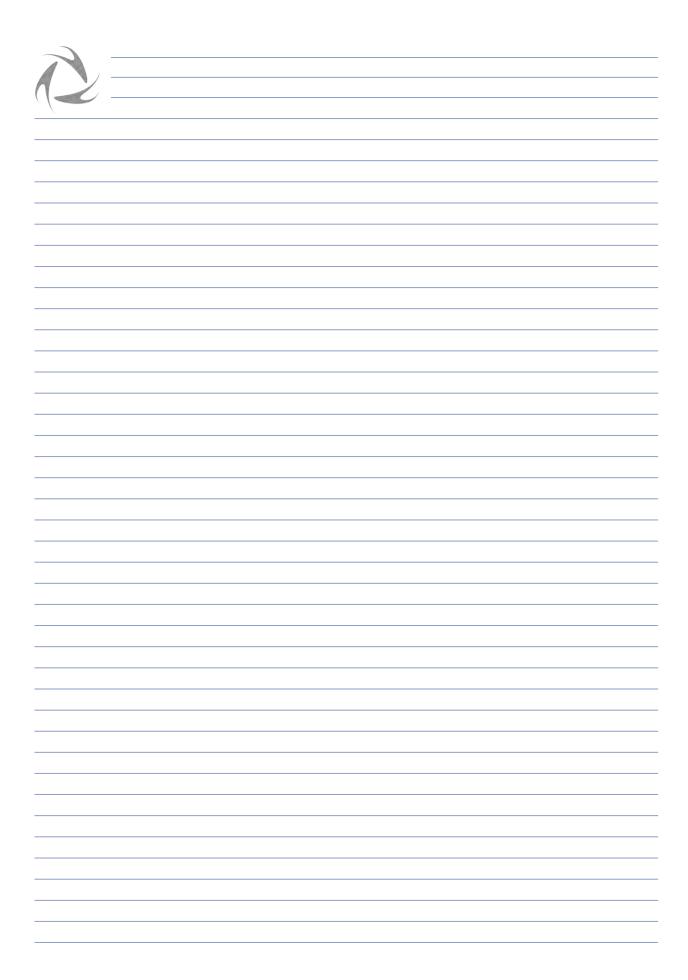
















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POSTURAL ANALYSIS

VIRTUAL REALITY SYSTEM FOR NEUROMOTOR REHABILITATION

SPORT TEST SYSTEMS

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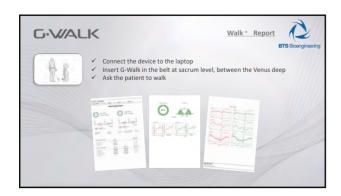


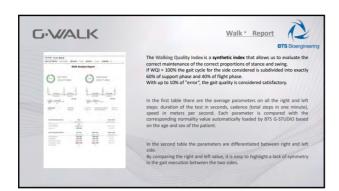


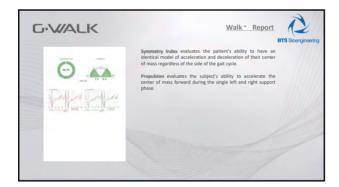


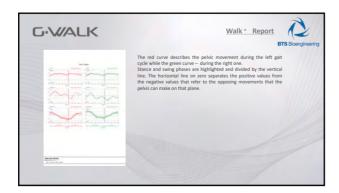


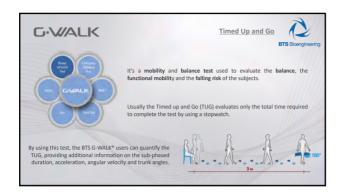


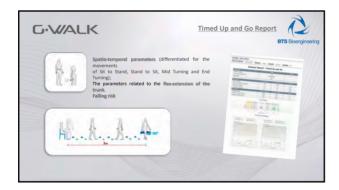




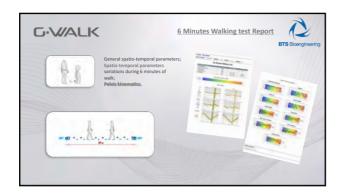




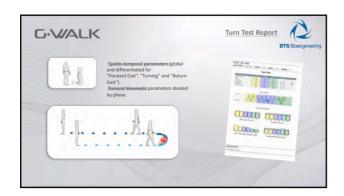




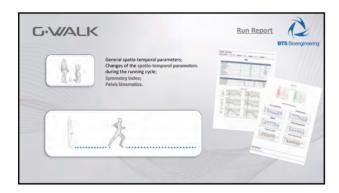


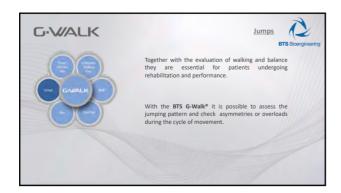




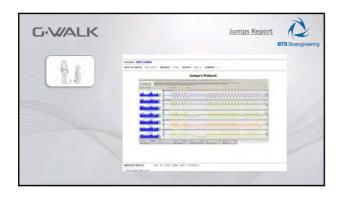




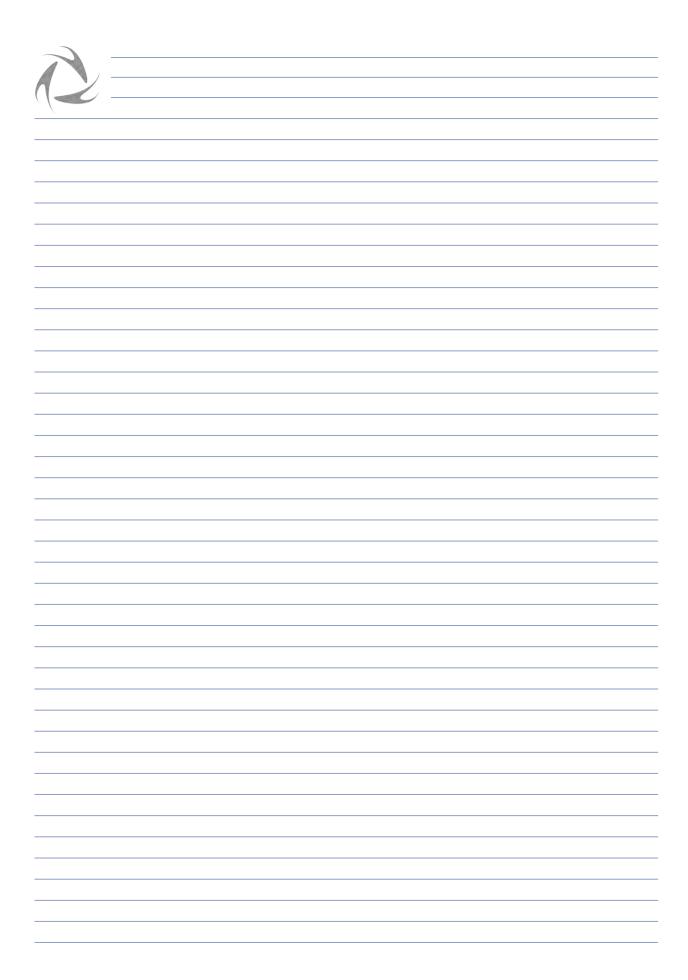


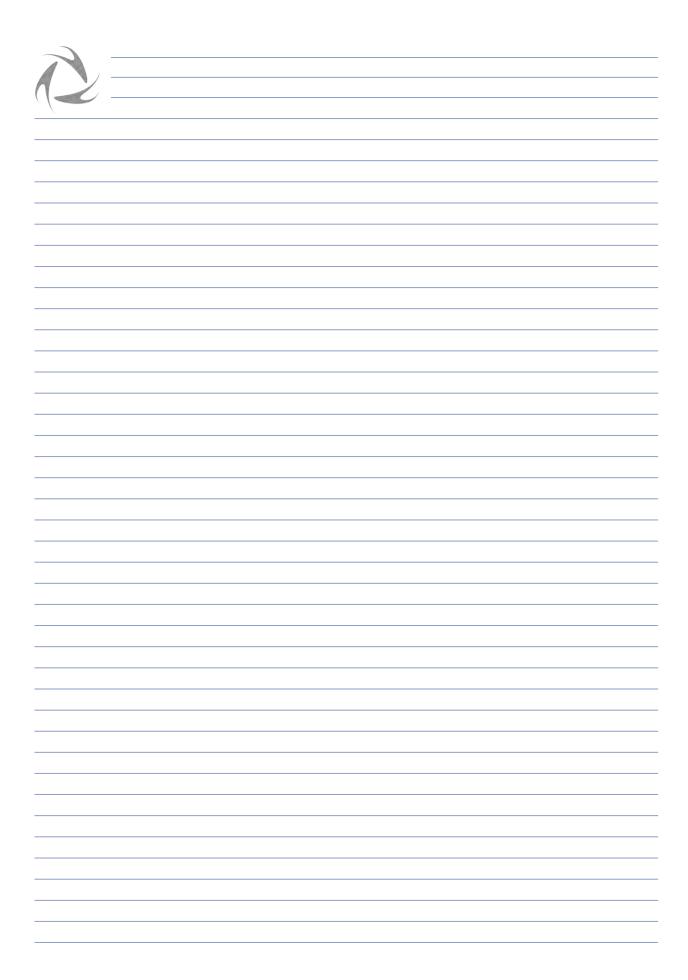
















MOTION LAB

SURFACE EMG FUNCTIONAL PROTOCOLS



POSTURAL ANALYSIS

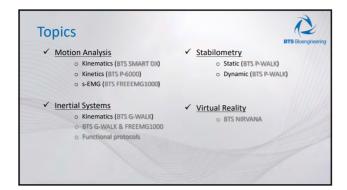
VIRTUAL REALITY SYSTEM FOR NEUROMOTOR REHABILITATION

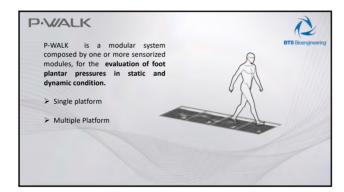
SPORT TEST SYSTEMS

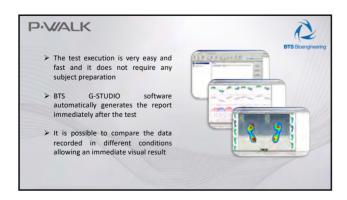
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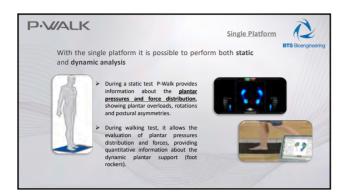
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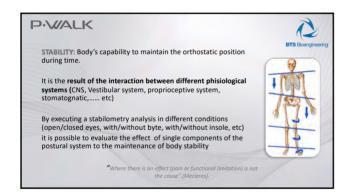


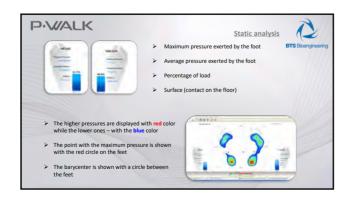




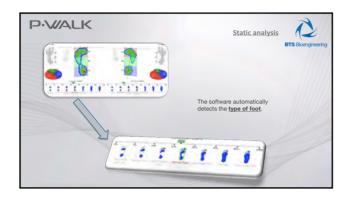


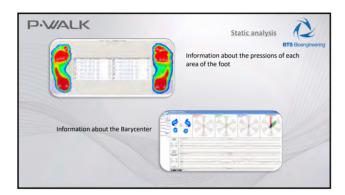


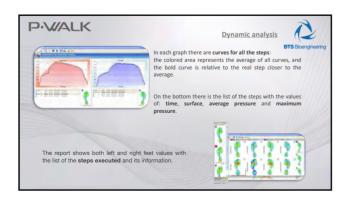








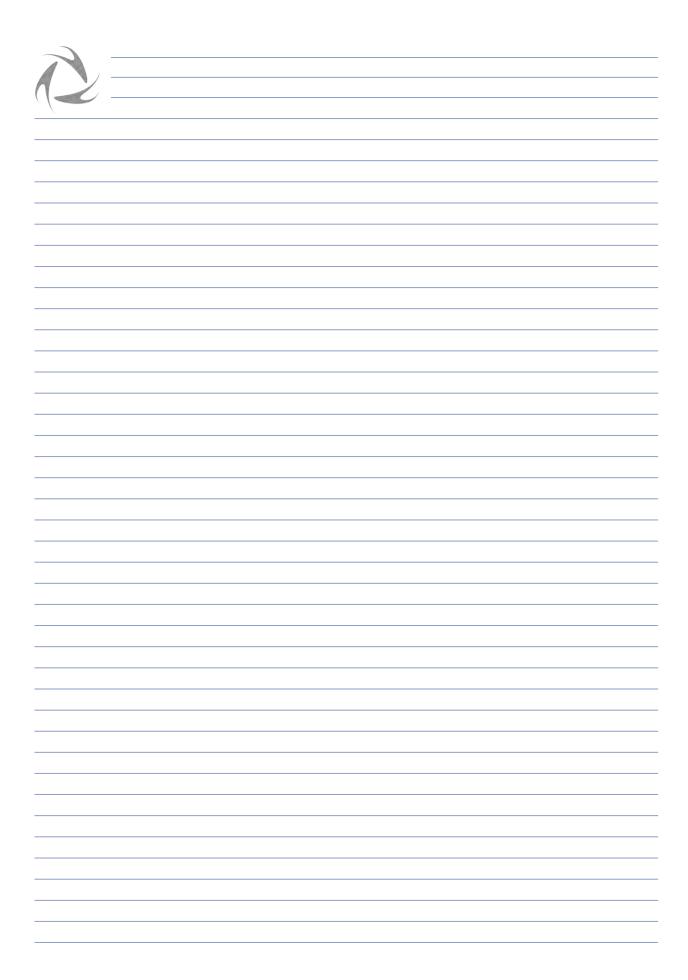
















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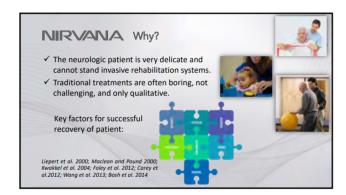




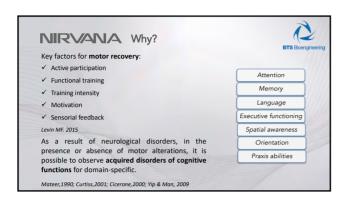


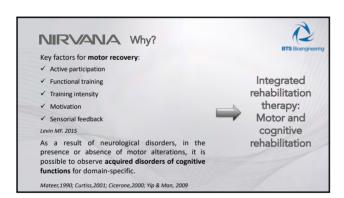


Immersive reality system for the motor and cognitive neurorehabilitation Patients: • of any age • with motor and cognitive deficits of the lower and/or upper limbs, trunk resulting from: • Brain injury (Post stroke, cranioencephalic traumas, brain tumours) • Various forms of cerebral palsy (ICP) • Neurodegenerative diseases (Parkinson's disease, multiple sclerosis, Alzheimer's disease) • Developmental disorders, Disorders of memory and attention, Autism spectrum disorder. Speeds up and improves the rehabilitation process through the active involvement of the patient.

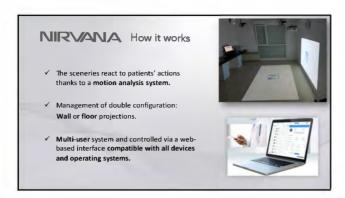










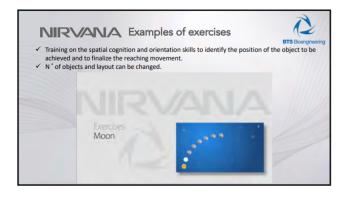


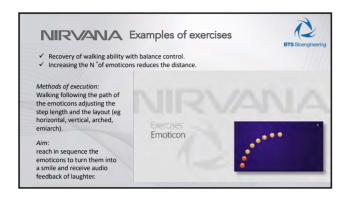


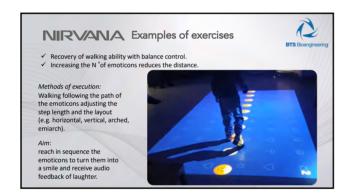


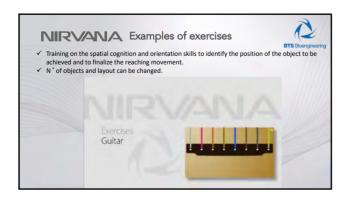


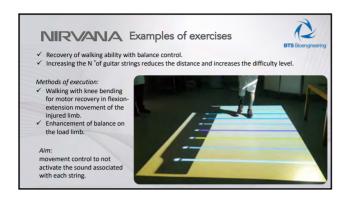


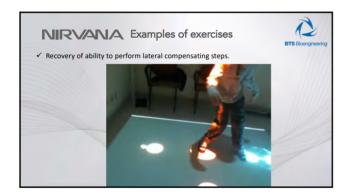




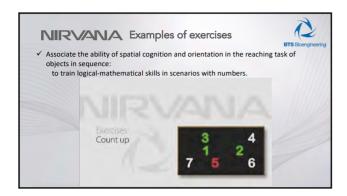


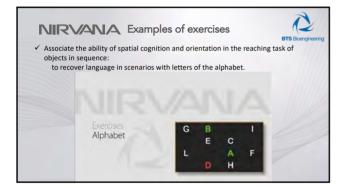


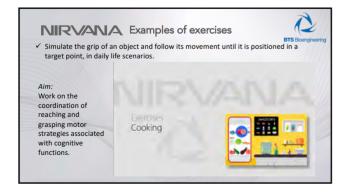






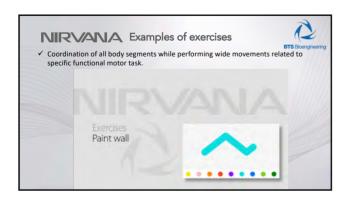




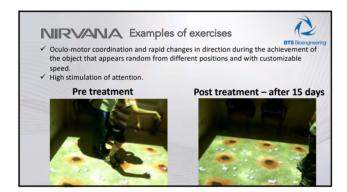


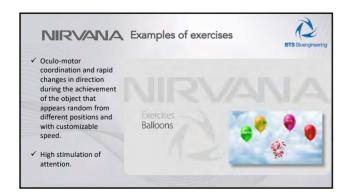


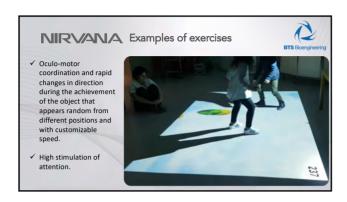


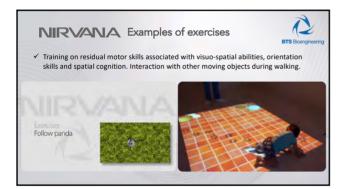


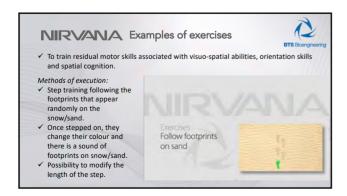


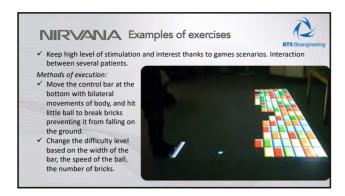


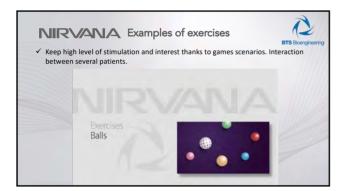


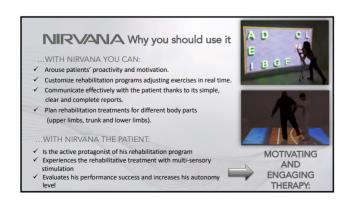




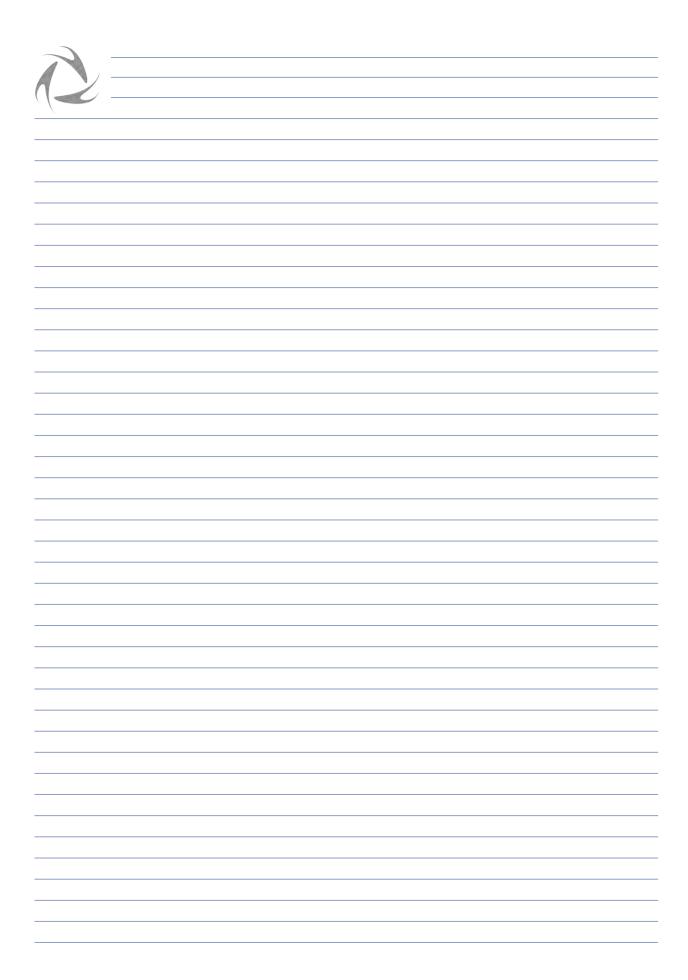












ANNEX 1 - UEMS - Position Paper

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New technologies designed to improve functioning: the role of Physical and Rehabilitation Medicine Physician

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Introduction

The growth in rehabilitation practice in all its fields, applications and settings, is showing increasingly strong interaction with the general increase in the potential of technology and its innovative applications. (1)

Nevertheless, it should be stressed that the use of machinery has always been a fundamental mainstay of rehabilitation practice (Physical and Rehabilitation Medicine, involving the whole environment around disabled people), as it was in the past with physical exercises, physical modalities, and many other activities that employed physical and technological means such as Aids, Prostheses and Orthotics.(2-3-4)

Currently the new possibilities offered by technologies support continuous development for these traditional rehabilitation tools and continuous extension of their applications toward the better recovery of functioning and health for any person with disability. (5-6-7)

On the other hand, the peculiarity of new technological equipment and methodologies for evaluation, but mainly for treatments, is interacting actively and profoundly with rehabilitation practices, very often modifying very deeply many previously shared theoretical, clinical and management paradigms.

So, the many different applications of technologies in therapeutic interventions are the "core" of the prospects for this Position Paper.

Another difficulty arises from the current imperfect classification of the types and categories of these devices and apparatus with regard to the variability and so many differences in characteristics, utilization, aims, etc.

Until now there has not been full consensus on which machines can be qualified as robots, but there is general agreement among experts and the public that "robots tend to do some or all of the following: move around, operate a mechanical limb, sense and manipulate their environment, and exhibit intelligent behaviour, especially behaviour which mimics humans or other animals". (4)

We may summarize as follows: robots have actuators and sensors, the action they perform is based on sensed status or environment and there is an intelligent reaction to this status or environment. Without intelligence it is "only" an automated object. In any case, they are used more and more in clinical activities in regard to daily care. This attention in the world of Robotic Rehabilitation is also demonstrated by the steady increase of publications on this topic, it is possible to select more than 900 articles in this scientific field in pub med in the last five years. In June 2013, 33 studies regarding this topic were recorded on the website Clinical Trial.Gov.

On the other hand, Assistive Technology (AT) or better recently Assistive Product is defined as "any item, piece of equipment, or product system whether acquired commercially off the shelf, modified or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities. It is a broad range of devices, services, strategies, and practices that are conceived and applied to ameliorate the problems faced by individuals who have disabilities." (8)

AT devices are tools for enhancing the independent functioning of people who have disabilities. They range from low-tech aids, such as built-up handles on eating utensils, to high tech devices such as computerised communication systems, alternative access systems or powered wheelchairs. The ultimate objective of AT is to contribute to the effective enhancement of the lives of people with disabilities and elderly people by helping to overcome and solve their functional problems, reducing dependence on others and contributing to integration into their families and society. (9)

This definition has several important elements. It emphasises the functional capabilities of individuals with disabilities as a result of the successful use of AT and is highly significant in terms of quality of life. It underscores the importance of assessing and supporting the unique needs of each individual and the context in which they will be applying AT.

If we wish to support and expand Physical and Rehabilitation Medicine it is fundamental to face these new aspects and show how these parts (new but completely incorporated into the scientific and practical role of PRM) are involved in our discipline evolution, the number of other professionals and technicians who could cooperate under the guidance of PRM doctors in the team to achieve the common aim of enriching scientific results and outcomes for people in treatment, and demonstrate how evaluation for research and certification regarding these new technologies and their clinical applications is at the heart of Physical and Rehabilitation Medicine.

<u>The purpose of this European Position Paper</u> is exactly to define a common all-round view of these problems, recognizing and understanding the main points regarding the Physical and Rehabilitation Medicine Specialist competences and activities.

- -Tools are scientific evidences (really very few at this time and needed to be expanded by our actions) but mainly our professional, clinical and management experiences and tasks.
- -Contents are about how rehabilitation facilities, programmes and interventions must be guided, about how education and research must be addressed and about how relationships with other professionals and with persons in care must be managed.

The document aims to underline the main key problems to propose a sort of common "agenda" at european level that can be carried out in any country, according to the different local situations, to support Physical and Rehabilitation Medicine in facing and guiding this evolution in the next years.

Key issues for Physical and Rehabilitation Medicine

This field takes concrete form in particular with projects and experiences for the use of innovative equipment and technological systems as supports, interaction or instruments for the realisation of various types of treatment for different purposes.

This interaction discloses great positive aspects, but also strong critical points due to the objective difficulty in correlating the actual needs of rehabilitation practices with appropriate responses on the part of technological research, as well as verification of the efficacy and efficiency of these innovations.

Really strong and rapid are the development and diffusion of these instruments in any country; scientific literature and in the same time any common information mean (Internet, TV, newspapers, etc.) are diffusing expectations among health systems, patients, families and disabled people's associations.

So these positive or critical aspects must be faced and solved as soon as possible.

A) Lack of complete clinical instructions

The first highly critical point is often (and for much of the equipment on the market) that there are no specific clinical elements of rehabilitation evidence to support the proposals companies introduce. Often there is only basic simple kinesiological, static-mechanical or neuro-functional evidence; in other cases there are only cognitive, behavioural, sensorial and relational elements, which are however very simple and elementary and are definitely not correlated to overall processes of understanding, learning and functional acquisition for recovery in functioning and participation. (10-11-12-13-14)

The increasingly prolific references do not yet offer suitable evidence for the many different applications.

In this sense, there is a great need for overall rehabilitative verifications on existing equipment, as well as rehabilitative research to better orient companies' technological applications in future (to modify existing or create new ones.

Moreover, some great positive prospects (to be developed) also emerge:

- -firstly, the possibility to have new tools with which to study and clarify modalities of therapeutic interventions, learning recovery and evidence in our clinical activities;
- -the possibility to guarantee greater homogeneity and measureability of treatments, as well as the relative effects and functional results;
- -the possibility, therefore, to realise wide-ranging significant clinical studies and bring out evidence of a biomechanical and functional nature and on individual performance.

B) Needs for new form of organization and economic recognition

Other critical elements in this phase turn up in the field of management and organisation in any facility, in any individual rehabilitation programme of treatment, and mainly regarding the needed Physical and Rehabilitation Medicine Specialist medical detailed prescription to apply these instruments, but also to obtain the right resources that this development requires. (15-16-17) As a matter of fact, very often these new modalities for treatment do not have specific recognition, just as if they were the same as other "traditional" methods: one of the most important causes is previous point A, but the financial crises in Health Services in many countries are also important.

Therefore limitations and differences arise among Rehabilitation Centres that can or cannot equip themselves with this innovative machinery, giving rise to doubts about disparities in treatment among the many types of persons with disabilities and their productive use of treatments. (17) Moreover, some great positive aspects (to be developed) also emerge:

- -The possibility to implement the different forms of distance /home -rehabilitation on a large scale, understood as an appropriate form of continuity and effectiveness of treatments, integrating them with the environment, individual and motivational lifestyles of persons who are deeply and actively involved .(18-19-12)
- A real possibility to increase care in relation to the multiplication of demand on the part of persons with disabilities, without excessive conflict regarding the costs that the use of personnel only would produce.

C) Inclusion of items concerning new technologies in educational programmes (basic and continuous)

Another critical element that emerges is the objective need to modify the contents of training for rehabilitation team personnel to promote appropriate and widespread use of technological equipment in rehabilitative treatment, as well as the organisation of various activities in the different temporal phases of treatment. Educational programmes (universitary or not) in PRM unfortunately in many countries should not pay great attention in order to include in the curriculum arguments concerning new technologies. This field of study for students should also include phases of direct clinical experiences in areas where technological systems are used both for evaluation and treatment in the patients.

The relationship between PRM and patients is also modified with respect to the substantial aspects of accepting patients for care and therapy and conducting the treatment between patient and health professionals. The change for PRM is mainly in research and defining new clinical paradigms, protocols and guidelines to add to previous knowledge. (18-20-21)

The question now arises as to whether this equipment can replace specific categories of operational personnel (Physiotherapists, Speech and Language Therapists, Occupational Therapists), perhaps partially regarding some traditional activities, or maybe partially substitute (Tele-rehabilitation) rehabilitative settings where therapeutic programmes were traditionally carried out.

In analysing relations between operational personnel and equipment, the theme of the "difficulty" of performing work is also posed. This tends to occur with Physiotherapists, Speech T., Occupational T., etc and is also one of the elements of adaptation for patients (due to their difficulty) in their progress in performing exercises.

Machinery, on the other hand, is not subject to these adaptations and we should imagine further "intelligent" evolution to enable it to adapt productively to reactions of persons undergoing therapy. Another aspect (only a brief note but the point has broad scientific contents for patients and professionals) is the "fatigue" involved in training and the single exercises which modify repetitions, strength, character, etc. Fatigue can underline or involve aspects regarding attention (not only on the patient's part), participation and motivation.

Obviously machines do not feel fatigue! But it could be necessary to adapt the activity programmes on the machinery to avoid problems connected with risks of fatigue for patients during training.

So the problem is precisely the specific (new) competence of operational personnel, who can supervise and guarantee the precision of these therapeutic procedures. Certainly this is something quite new regarding the previous traditional role of professionals, i.e. providing treatment directly "by hand".

These professionals need new education of a quite different nature, a new role in the global management of treatment programmes, times, measurements and responsibilities, a different

cooperation in the Team and with other professionals more technical as programmers and engineers.

D) Care relationship

Nowadays, due to the effects of this equipment, the position and attitude of patients towards their recovery programme and the proactive behaviour they must endeavour to implement in its realisation is very often substantially modified as well.

The primary need is therefore confirmed for global and individual care for the person in the Individual Rehabilitation Project, in order to bring every intervention to a therapeutic and evaluation synthesis. This situation is much more complex and requires a solid role for responsibility in the hands of Physical and Rehabilitation Medicine Specialists, obviously regarding prescriptions for technological treatments, evaluations of results and coordination with other interventions in the recovery program. (9)

Another important role for them is also related to the importance of its constructive relationships with those who design technological systems (Bioengineers, Engineers and other Technicians). The challenge of these years is precisely the construction of new devices that arise from the daily clinical needs.

The equipment is sometimes included as a "support and multiplier" to extend activities and treatments at every level, maintaining a relation with the "traditional" care program regarding different clinical situations. On the contrary, machines can show results over time, for example, by creating a sort of "positive game" for patients, directly communicating to them and thereby excluding professionals.

In other occasions the equipment is introduced as an entirely new potential (which would otherwise not be possible) to perform rehabilitative training that must in any case be included in organic care programmes, under the prescription and guide by the Physical and Rehabilitation Medicine Specialist and with the cooperation of adequately prepared operators. (18-2-20-22)

Therefore, in both cases the equipment immediately creates a new situation in which information, involvement and communications about results must be up-graded towards patients, family and care-givers: it is also better with regard to the active role of the person in care. (23)

Obviously, this last point, like the previous one, is also strongly connected to and based on the first point regarding the lack of clinical evidence on rehabilitation.

Conclusions

As previously explained the purpose of this <u>European Position Paper</u> is to synthesize a common allround view aiming to underline the main key problems, regarding the development of Physical and Rehabilitation Medicine Specialist role.

The document suggest a sort of common "agenda" that can be carried out at european level and in any country, according to the different local situations, to support Physical and Rehabilitation Medicine in facing and guiding this evolution in the next years.

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References:

- 1- Scherer MJ. Editorial. The change in emphasis from people to person: Introduction to the special issue on assistive technology. Disability and Rehabilitation 2002; 24(1/2/3):1-4.
- 2- Bernhardt J, Thuy MN, Collier JM, Legg LA. Very early versus delayed mobilization after stroke. Cochrane database Syst Rev 1009 (1): CD006187: 489-90
- 3- Donkin BH, Strategies for stroke rehabilitation. Lancet Neurol 2004; 3: 528-36
- 4 Joseph F. Engelberger Wikipedia.
- 5- Holden MK. Virtual environments for motor rehabilitation: review. 26. Cyberpsychol behav 2005; 8: 187–211.
- 6- Mehrholz J et al. Electromechanical and robot-assisted arm training for improving arm function and activities of daily living after stroke. Cochrane Database of Syst Rev 2008 (4): CD006876
- 7- Scattareggia MS, Nowe` A, Zaia A, et al. H-CAD. A new approach for home rehabilitation. Int J Rehabil Res 2004; 27 (Suppl. 1):110–11
- 8 Andrich R. www.aaate.net
- 9- Martin J K, Martin L G, Stumbo N J, Morrill J H (2011): The impact of consumer involvement on satisfaction with and use of assistive technology. Disabil Rehabil Assistive Technology 6(3):225-24.
- 10- Colombo R, Pisano F, Mazzone A, Delconte C, Micera S, Carrozza MC, Design strategies to improve patient motivation during robot-aided rehabilitation. J Neuroeng Rehabil 2007; 4:3: 1-12
- 11- Huijgen B., Vollenbroek-Hutten M., Zampolini M., Bernabeu M. Feasibility of home-based telerehabilitation system compared to usual care: arm/hand function in patients with stroke, traumatic brain injury and multiple sclerosis Journal of Telemedicine and Telecare- 14 2008, 5 -20
- 12- Heinzelmann PJ, Williams CM, Lugn NE, Kvedar JC. Clinical outcomes associated with telemedicine/telehealth. Telemed J E Health 2005;11:329-47
- 13- Legg L, Drummond A, Leonardi-Bee J, et al. Occupational therapy for patients with problems in personal activities of daily living after stroke: systematic review of randomized trials. BMJ 2007;335:922
- 14- Sale P, Franceschini M, Waldner and Hesse S: Use of the Robot Assisted Gait Therapy in rehabilitation of patients with stroke and spinal cord injury. Eur J Phys Rehabil Med 2012 1:Vol 48
- 15- Hayward K, Barker R, Brauer S. Interventions to promote upper limb recovery in stroke survivors with severe paresis: a systematic review. Disabil Rehabil 2010; 32: 1973-86

- 16- Piron L., Zampolini et al M Exercises for paretic patients' upper limbs after stroke: a combined virtual reality and telelmedicine approach. J Rehabil Med 2009; 41: 1016–1020
- 17- Wagner TH, Lo AC, Peduzzi P, Bravata DM, Huang GD, Krebs HI, Ringer RJ, Federman DG, Richards LG, Haselkorn JK, Wittenberg GF, Volpe BT, Bever CT, Duncan PW, Siroka A, Guarino PD. An economic analysis of robot-assisted therapy for long-term upper-limb impairment after stroke. Stroke. 2011 Sep; 42(9): 2630-2. Epub 2011 Jul 14.
- 18- Broens TH, Huis in't Veld RM, Vollenbroek-Hutten MM, Hermens HJ, van Halteren AT, Nieuwenhuis LJ. Determinants for successful telemedicine implementations: a literature study. J Telemed Telecare 2007;13:303–9
- 19- Forducey PG, Ruwe WD, Dawson SJ, Scheideman-Miller C, McDonald NB, Hantla MR. Using telerehabilitation to promote TBI recovery and transfer of knowledge. NeuroRehabilitation 2003;18:103–11
- 20- Egner A, Phillips VL, Vora R, Wiggers E. Depression, fatigue, and health-related quality of life among people with advanced multiple sclerosis: results from an exploratory telerehabilitation study. NeuroRehabilitation 2003;18:125–33
- 21-You SH, Jang SH, Kim YH, Hallett M, Ahn SH, Kwon YH, et 25.al. Virtual reality-induced cortical reorganization and associated locomotor recovery in chronic stroke: an experimenter-blind randomized study. Stroke 2005; 36: 1166–1171.
- 22- Mehrholz J, Werner C, Kugler J, Pohl M. Electromechanical-assisted training for walking after stroke. Cochrane Database of Syst Rev 2007 (4): CD006185
- 23- Kwakkel G, Kollen BJ, Krebs HI, Effects of Robotic-assisted therapy on upper limb recovery after stroke: a systematic review. Neurorehabil Neural Repair 2008; 22: 111-21

ANNEX 2 - Indice dei contenuti

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La Riabilitazione robot-assistita degli arti superiori

I Criteri:

La ricerca sistematica della letteratura è stata condotta fino al giugno 2010 e successivamente ampliata al 2016, inserendo nei diversi motori di ricerca le parole chiave "rehabilitation", "upper limb", "randomized trial" e "robot".

Per quanto riguarda l'utilizzo di Google Scholar la strategia di ricerca per i robot dedicati agli arti superiori si è così articolata: inizialmente è stata eseguita una prima selezione con le parole sopraccitate; successivamente, essendo il numero di articoli presenti cospicuo, abbiamo applicato un limite temporale (2007-2016). Questo accorgimento ci ha permesso di ridurre il numero di articoli da 969 a 476. Tale periodo è stato scelto in base ad alcuni lavori di review già presenti in letteratura (6,7,8).

Come criteri di inclusione sono stati considerati la lingua inglese, la presenza di una comparazione pre e post trattamento e/o studi con gruppo di controllo, infine la misurazione degli outcome con scale di funzionalità e disabilità. Gli articoli che descrivevano l'utilizzo del dispositivo robotico in soggetti sani sono stati esclusi, mentre altri articoli, pur non essendo randomizzati e controllati sono stati presi ugualmente in considerazione in quanto contenenti informazioni utili al lettore e/o interessanti risultati.

I Risultati:

Con i criteri di selezione sopra esposti sono stati inclusi nella revisione 33 articoli.

Dai risultati raccolti è emerso che i robot dedicati agli arti superiori vengono impiegati quasi esclusivamente per il trattamento di pazienti con esiti da stroke, solamente uno studio (9) ha preso in considerazione soggetti con esiti di trauma cerebrale. La Tabella I riporta i dispositivi più frequentemente utilizzati e le loro caratteristiche principali. Si tratta in genere di dispositivi dedicati al recupero motorio di specifici segmenti articolari, in particolare la maggior parte è indirizzata al recupero funzionale di spalla e gomito (articolazioni prossimali) ed una minoranza è dedicata al recupero delle articolazioni distali (polso e mano). I dispositivi robotici si differenziano per le diverse modalità riabilitative che possono essere messe in atto. Esistono tre diversi programmi di funzionamento: la modalità passiva (movimento eseguito dal robot con velocità e range di movimento predefiniti), la modalità assistiva (il robot aiuta il soggetto quando non riesce a completare autonomamente il movimento) e la modalità resistiva (il lavoro eseguito dal soggetto avviene contro resistenza

o perturbazioni generate dal robot stesso) (10). Alcuni di essi consentono infine l'esecuzione di compiti motori bimanuali.

Tab. I Caratteristiche dei dispositivi robotici dedicati agli arti superiori

Gli studi randomizzati controllati includevano in totale 744 pazienti, mentre ulteriori 225 pazienti hanno partecipato a studi non controllati.

I protocolli riabilitativi prevedevano da un minimo di 3 ad un massimo di 12 settimane di trattamento, mentre la frequenza settimanale variava da 3 a 7 sessioni. L'intensità di ogni singolo trattamento variava da un minimo di 15 minuti ad un massimo di 170 minuti (Tab. II).

Gli studi RCT includevano un gruppo di controllo (GC) che effettuava un trattamento riabilitativo di durata pari oppure inferiore rispetto ai soggetti del gruppo sperimentale (GR) trattati con il dispositivo robotico. In alcuni casi i soggetti del GC ricevevano un trattamento fisiochinesiterapico alternativo al robot, in altri erano solamente "esposti" al dispositivo robotico per pochi minuti (trattamento cosiddetto "sham").

Tab. II Tabella riassuntiva delle caratteristiche dei protocolli riabilitativi con dispositivi robotici dedicati agli arti superiori

Tutti gli studi valutavano l'efficacia del trattamento robot-assistito attraverso l'impiego di scale cliniche standardizzate che monitoravano il recupero motorio dell'arto superiore e il recupero dell'autonomia del soggetto nell'esecuzione delle attività di vita quotidiana. In generale, le scale di valutazione maggiormente utilizzate negli studi erano la scala Fugl-Meyer (F-M), la scala Motor Power (MP) o MRC, la scala Motor Status Score (MSS), la scala di Ashworth per la valutazione del tono muscolare e la scala FIM per la valutazione del recupero funzionale. Tali scale di valutazione saranno oggetto della discussione dei risultati osservati nei vari articoli inclusi nella presente revisione.

Gli studi individuati coinvolgevano pazienti in differenti fasi dello stroke: acuta, subacuta e cronica. A causa della diversa evoluzione del quadro clinico a distanza dall'esordio dei sintomi i risultati sono stati suddivisi tra fase acuta/subacuta e fase cronica.

Stroke in fase acuta e subacuta

^{*} in 9 articoli non è presente il gruppo controllo

Le prime settimane dall'evento acuto sono caratterizzate da miglioramenti neurologici spontanei; molti studi supportano l'ipotesi che il recupero neurale e funzionale avvenga soprattutto nei sei mesi successivi allo stroke, mentre la funzione neuromuscolare, la mobilità e l'attività giornaliera continuano a migliorare durante il periodo successivo.

I pazienti colpiti da stroke necessitano, pertanto, di una precoce presa in carico per poter iniziare una riabilitazione intensiva specialistica non appena ottenuta una certa stabilità clinica; in questo quadro ben si inserisce l'utilizzo di dispositivi robotici al fine di incrementare e ottimizzare il trattamento riabilitativo.

Efficacia del trattamento. Il dispositivo NeReBot è l'unico sistema progettato specificamente per poter essere agevolmente impiegato anche a letto del paziente, quindi in una fase clinica molto precoce del trattamento riabilitativo (11,12). I risultati dei due studi selezionati mostravano un miglioramento significativo nel gruppo sperimentale a fine trattamento valutato attraverso le scale F-M e MP, limitato alla sola sezione riguardante l'arto superiore. E' plausibile ritenere che i pazienti del GR mostrino risultati migliori in quanto la durata del trattamento era superiore a quella dei pazienti del GC. Nonostante questo limite, lo studio ha dimostrato la sicurezza e la praticità nell'utilizzo di tale dispositivo robotico per la movimentazione passiva nella fase acuta dello stroke.

Altri dispositivi sono stati impiegati per il trattamento di pazienti in fase subacuta (BiManuTrack, MIME, MITMANUS e RehaSlide); oltre al trattamento robotico gli studi includevano altre tipologie di trattamento quali: fisiochinesiterapia tradizionale, stimolazione elettrica funzionale (FES), terapia occupazionale e cicloergometro per gli arti superiori.

Da un esame globale emerge che la funzione motoria valutata con la scala F-M mostra un miglioramento sia nel gruppo sottoposto a terapia robot-assistita che nel gruppo controllo, (non esistono differenze significative tra i due gruppi). Quando vengono considerate le sezioni della scala dedicate a spalla e gomito, in uno studio (13) si otteneva un miglioramento significativo a favore del GR. Nello studio relativo al dispositivo BiManu Track (14) i soggetti trattati con robot mostravano un miglioramento significativo della scala FM, delle sue sezioni prossimale e distale, e della scala MP.

Alcuni studi (13,15,16,17,18) valutavano la funzionalità motoria prossimale dell'arto superiore attraverso la scala MSS. Grazie alla maggiore sensibilità di questa scala tutti gli studi, eccetto uno (17), dimostravano un miglioramento significativo nel gruppo sperimentale.

Effetti sul deficit di forza. Tre studi su 5 (14,15,16,18,19) mostravano che il GR evidenziava un recupero prossimale del deficit di forza (valutato attraverso MP e MRC) che risultava statisticamente superiore rispetto al GC.

Intensità del trattamento. L'analisi della intensità del trattamento, come sottolineato in precedenza, ha mostrato che in alcuni studi (15,16,18) i pazienti del GR ricevevano un'intensità di trattamento (circa un'ora) superiore a quella del GC in cui i pazienti risultavano esposti al robot solo per alcuni minuti senza ricevere assistenza; inoltre, il tempo rimanente non era speso per effettuare un trattamento riabilitativo alternativo.

Confronto con altre tipologie di trattamento. L'allenamento con il dispositivo robotico BiManuTrack (14) era in grado di produrre un miglioramento statisticamente superiore a quello con stimolazione elettrica funzionale (FES) sia nel controllo motorio che nel recupero del deficit di forza dell'arto superiore; secondo gli autori, i fattori determinanti di tale differenza erano da imputare ad una maggiori un'intensità di trattamento e coinvolgimento dei pazienti.

Un altro studio dello stesso gruppo di ricerca, in cui un gruppo di pazienti trattati con dispositivo RehaSlide (19) era paragonato con un GC trattato con FES, mostrava differenze significative a favore del GR solo da un punto di vista funzionale (Box & Block Test), mentre l'outcome primario (scala F-M) non mostrava differenze significative tra i due gruppi. Nello studio di Lum (13) i pazienti appartenenti al GR, paragonati ad un GC trattato con fisiochinesiterapia tradizionale, mostravano un maggior recupero del deficit motorio e delle sinergie. Infine in uno studio con il dispositivo MITMANUS (17), la terapia robot assistita era messa a confronto con l'allenamento al cicloergometro e con ergoterapia. Nonostante le evidenti differenze nella tipologia di terapia fornita ai pazienti i risultati non mostravano differenze significative tra i gruppi. Secondo gli autori questi risultati sembrano suggerire che il tipo di movimento compiuto dall'arto superiore, così come il numero di ripetizioni, non abbiano un ruolo preponderante durante la riabilitazione dello stroke in fase subacuta e acuta (17).

Effetti sul tono muscolare. Il tono muscolare valutato con la scala di Ashworth risultava invariato (11,12) o migliorato (17), quindi si può affermare che globalmente l'utilizzo dei dispositivi robotici durante questa fase dello stroke è sicuro.

Effetti sul dolore. Due studi (15,17) valutavano l'effetto della terapia robotica sul dolore. Entrambe hanno dimostrato l'assenza di variazioni significative. In un caso (17) si osservava una diminuzione della sintomatologia algica.

Effetti sull'autonomia funzionale. L'autonomia nelle attività di vita quotidiana è stata valutata con l'impiego della scala FIM (15,16,17). I risultati ottenuti mostrano sempre un miglioramento significativo: in due studi esso risultava indipendente dal tipo di trattamento riabilitativo effettuato (15,17), mentre nello studio di Volpe (16) emerge una differenza significativa a favore dei pazienti trattati con robot. Questi risultati sono incoraggianti, essendo il recupero del gesto funzionale uno degli obiettivi principali del progetto riabilitativo individuale. In futuro sarebbe auspicabile un utilizzo più esteso della scala FIM o analoghe in particolare in quei dispositivi che coinvolgono la parte distale dell'arto superiore, quali il BiManuTrack.

Effetti a lungo termine della terapia robotica. Gli studi che indagano il mantenimento dei risultati ottenuti a distanza sono 4 (13,14,18,19). I miglioramenti della funzionalità motoria e del deficit di forza valutati rispettivamente con la scale F-M e MRC risultano conservati a distanza di tre mesi (14,19) e non mantenuti a distanza di sei (13). Da sottolineare che tutti e tre questi studi hanno utilizzato un tipo di dispositivo robotico che prevedeva un allenamento bilaterale. Si potrebbe ipotizzare una durata limitata nel tempo del recupero della funzione motoria, in termini di esecuzione di movimenti complessi coinvolgenti l'arto superiore nella sua globalità e del recupero stenico. L'eventuale determinazione di questo lasso di tempo sarebbe utile ad esempio ai fini della programmazione di successivi trattamenti riabilitativi, finalizzati al mantenimento e al miglioramento dei risultati raggiunti. Uno studio (18) ha ricontattato e rivalutato un piccolo gruppo di pazienti (dodici) a distanza di tre anni dalla fine della terapia robotica. I miglioramenti ottenuti sembravano essere mantenuti limitatamente ai gruppi muscolari allenati con il robot (spalla e gomito). A parte vanno citati i risultati a distanza degli studi (11, 12) in cui il dispositivo NeReBot veniva impiegato su pazienti in fase acuta: in entrambi i miglioramenti ottenuti sono interamente mantenuti dopo tre mesi e conservati in parte dopo otto.

Poiché il numero di articoli con valutazione a distanza è ridotto non è possibile effettuare un confronto tra i diversi dispositivi utilizzati. Il numero esiguo di studi non permette pure di individuare modalità di training o tipologie di robot più efficaci nel trattamento riabilitativo in questa fase dello stroke. I dati presenti in letteratura sembrano suggerire un trend positivo verso i dispositivi con possibilità di training bilaterale o combinato per quanto riguarda il recupero della funzione e della potenza motoria degli arti superiori. Questa tendenza è anche supportata da un recente studio (20) che mette a confronto l'allenamento bilaterale agli arti superiori con quello monolaterale, senza l'ausilio di dispositivi robotici. I risultati ottenuti mostrano: una migliore efficienza in termini spaziali e temporali durante l'esecuzione di

compiti mono e bilaterali, una diminuzione delle correzioni durante l'esecuzione di compiti bilaterali, un miglioramento significativo nella F-M, maggiore nei soggetti sottoposti a training bilaterale; nessuna differenza è stata dimostrata nella scala FIM (Tab. III).

Tab. III Tabella riassuntiva dei risultati sulla riabilitazione post-stroke robot-assistita degli arti superiori in fase acuta/subacuta

Legenda: GR: Gruppo sperimentale con trattamento Robotico; GC: gruppo controllo;

FES: stimolazione elettrica funzionale; FKT: fisiokinesiterapia; TO: Terapia

Occupazionale; F-M: Fugl-Meyer Scale, MSS: Motor Status Score; MP: Motor Power;

FIM: Functional Indipendence Measure.

Stroke fase cronica:

In letteratura gli articoli riguardanti la riabilitazione dello stroke in fase cronica sono più numerosi, così come i dispositivi robotici impiegati. I robot interessano il distretto prossimale e/o distale dell'arto superiore con modalità di training differenti.

Gli studi possono essere suddivisi in due grandi gruppi: quelli in cui è presente un gruppo di controllo (GC) e quelli in cui è presente il solo gruppo sperimentale (GR) trattato con il dispositivo robotico. Per meglio sintetizzare i risultati riporteremo essenzialmente i risultati ottenuti negli studi con GC, mettendo in evidenza solo alcuni aspetti peculiari risultanti dagli studi eseguiti con solo gruppo sperimentale.

La tabella IV riassume le caratteristiche principali ed i risultati degli studi con gruppo di controllo e trattamento riabilitativo alternativo al robot.

Efficacia del Trattamento. La funzione motoria dell'arto superiore valutata con la scala F-M mostrava sempre un miglioramento in tutti i pazienti indipendentemente dal tipo di trattamento; solo in due studi i risultati erano a favore del GR (10,21). Questa differenza significativa si osservava anche in due ulteriori studi (22,23) che applicavano il dispositivo MIME, quando veniva considerata solo la sezione della scala dedicata a spalla e gomito. Solo due studi avevano tra gli obiettivi la valutazione del recupero della parte distale dell'arto superiore (23,24); entrambe non mostravano miglioramenti significativi. Il dato risulta prevedibile in quanto i dispositivi robotici impiegati erano indirizzati al recupero funzionale prossimale dell'arto superiore.

Due studi riguardanti il dispositivo GENTLE/S meritano una citazione separata in quanto i protocolli sperimentali risultavano costituiti da tre moduli della durata di 3 settimane ciascuno, alla fine dei quali veniva effettuata una valutazione della funzionalità motoria con scala F-M. I risultati hanno evidenziato un recupero maggiore durante la fase di trattamento con il dispositivo robotico (25,26). Da sottolineare lo studio di Takahashi (21) che valutava

il recupero motorio attraverso la scala ARAT (Action Research Arm Test) ed osserva una significatività nei risultati del GR, tale miglioramento tra l'altro risultava mantenuto anche nel follow-up.

Risultati analoghi a quelli su esposti sono stati ottenuti anche in quegli studi che non includevano un gruppo di controllo (solo GR) e che quindi prendevano in considerazione esclusivamente le valutazioni ad inizio e fine trattamento. Tali studi tra l'altro includevano la valutazione mediante scala MSS o altre scale che valutano la funzionalità dell'arto superiore.

Effetti sul deficit di forza. Il deficit di forza risultava sempre migliorato in tutti i pazienti sottoposti a trattamento riabilitativo; tale risultato appare statisticamente significativo nel GR in due studi (22,23) che, impiegavano il dispositivo MIME e nello studio (10) che utilizzava il dispositivo MEMOS.

Effetti sul tono muscolare. Come è già emerso per la fase acuta e subacuta il tono muscolare non variava, indipendentemente dal tipo di trattamento effettuato, anzi in alcuni casi (9,21) risultava diminuito. In un caso (27) dove era impiegato un robot destinato alla riabilitazione di gomito e polso (ARM Trainer) si osservava una diminuzione del tono valutato con la scala Ashworth che non risultava mantenuta nel controllo a distanza.

Effetti sul dolore. La sintomatologia dolorosa valutata in alcuni studi migliorava a fine trattamento (27,28,29), solo in un caso risultava invariata (30).

Effetti sull'autonomia funzionale. L'autonomia funzionale, quantificata attraverso la scala FIM, risultava valutata pochissime volte: negli studi (22,23) non mostrava alcun miglioramento significativo; solo nello studio (9) dove era applicato il dispositivo REHAROB con modalità passiva si osservava un miglioramento significativo della sezione motoria della scala, ma senza evidenziare differenze significative tra i due gruppi. Quando il recupero dell'autonomia nelle ADL era valutato con altre scale come ad esempio la Stroke Impact Scale (SIS) si osservava un miglioramento significativo in tutti i pazienti indipendentemente dal trattamento effettuato (31,32). Due studi (30,33) con solo GR mostravano un miglioramento dei pazienti trattati dell'autonomia nelle ADL. In uno di essi, in cui era impiegato il dispositivo ReoGo (30) tale guadagno veniva mantenuto a distanza di un mese. In ogni caso, la mancanza di utilizzo di scale comuni non permette di effettuare un confronto dei risultati osservati.

Effetti a lungo termine della terapia robotica. Le valutazioni a distanza effettuate nei diversi studi erano caratterizzate da un tempo di follow-up che variava da un minimo di un mese ad massimo di sei mesi. Globalmente si può affermare che i progressi ottenuti,

indipendentemente dal tipo di trattamento ricevuto, valutati in termini di miglioramento della funzione dell'arto superiore (F-M) e del deficit di forza erano mantenuti nel tempo.

Entrando nel dettaglio osserviamo che: nei due studi (31,21),dove erano impiegati robot destinati alla riabilitazione della parte distale, i miglioramenti della funzione della mano valutata con la scala SIS o con la scala ARAT erano mantenuti nel tempo, senza però mostrare differenze significative tra il gruppo sperimentale e quello di controllo. Nello studio (23) dove il controllo a distanza era effettuato a sei mesi si osservava che i miglioramenti valutati con la scala F-M non erano mantenuti. In effetti però emergeva un risultato statisticamente significativo nel recupero delle ADL del GR valutato con la scala FIM; guadagno che tra l'altro non risultava evidente a fine trattamento. Nello studio di Lo (32) i miglioramenti ottenuti a fine trattamento nei tre gruppi esaminati (robot, cure intensive, cure abituali) erano mantenuti nel tempo. Nel follow-up inoltre emergeva che il trattamento con robot o con cure intensive risultava superiore rispetto alle cure abituali. Analogamente nello studio di Staubli (34), i miglioramenti osservati con la scala F-M alla fine del trattamento con ARMinII risultavano mantenuti a distanza di sei mesi.

Altre modalità di training. Il numero di studi riguardanti i dispositivi con un training mirato alla parte distale e/o bilaterale è limitato, per tale motivo non è stato possibile fare emergere eventuali differenze con il gruppo più numeroso riguardante dispositivi robotici destinati alla parte prossimale in modalità monolaterale. Alcuni studi avevano come scopo quello di individuare una modalità di training ottimale per un miglior recupero del paziente; in particolare due di essi, confrontavano la modalità attiva-assistita con quella del training contro resistenza (29,35); tutti i pazienti coinvolti mostravano un recupero della funzionalità dell'arto superiore indipendentemente dal tipo di trattamento effettuato. L'unica differenza osservata era un miglioramento aspecifico a livello del polso e della mano rilevato tramite la scala MSS nei soggetti che si esercitavano contro resistenza.

La difficoltà nell'analisi comparata di tutti questi studi è la mancanza di un tratto comune nella valutazione dei vari aspetti del recupero della disabilità. Come già segnalato nella letteratura più recente, dall'analisi dei risultati emerge che il trattamento riabilitativo nello stroke in fase cronica determina comunque un miglioramento significativo delle prestazioni motorie, oggettivabile con valutazioni cliniche, sia a fine trattamento che a distanza. Diventa evidente quindi che la riabilitazione può risultare fondamentale anche nella fase cronica della malattia.

I risultati fin qui esaminati non mostrano una netta superiorità del trattamento con dispositivi robotici, anche se risultano spesso più efficaci nel recupero del deficit di forza e funzionale

della parte prossimale dell'arto superiore. In questa misura il robot sembra proporsi come trattamento integrativo e/o complementare al trattamento riabilitativo tradizionale. Dal momento che ci stiamo riferendo ad un fase dello stroke dove la riabilitazione è per lo più considerata un'attività di carattere non intensivo si può prospettare uno scenario in cui i robot o altri dispositivi con un impatto economico non elevato possano permettere una riabilitazione di gruppo con un minor dispendio di risorse o al domicilio del paziente per il mantenimento dei risultati conseguiti durante la fase di ricovero garantendo in tal modo la continuità delle cure.

Sarebbe infine auspicabile una maggiore uniformità nelle scale impiegate per valutare l'autonomia del soggetto sia a fine a trattamento sia a lungo termine.

A tale proposito va segnalato che alcuni studi (2,36,37,38), valutavano gli effetti del trattamento riabilitativo osservando la variazione di parametri del movimento: anche in questo caso troviamo un miglioramento. In particolare si osservano: una riduzione degli errori direzionali durante l'esecuzione del compito, e della velocità del movimento, un miglioramento dell'attivazione dei patterns muscolari dimostrati all'elettromiografia e un recupero dell'articolarità.

Tab.IV Tabella riassuntiva dei risultati sulla riabilitazione post-stroke robot-assistita degli arti superiori in fase cronica (articoli con GC)

Legenda: GR: Gruppo sperimentale con trattamento Robotico; GC: gruppo controllo; FES: stimolazione elettrica funzionale; FKT: fisiocinesiterapia; ChMcM: Chedoke-McMaster Upper Extremity Stroke Assessment Scale; RLA Test: Rancho Los Amigos Functional Test; SIS: Stroke Impact Scale; F-M: Fugl-Meyer Scale, MSS: Motor Status Score; MP: Motor Power; FIM: Functional Indipendence Measure.

Riabilitazione robot-assistita degli arti inferiori

Circa un quarto dei pazienti con esiti da ictus cerebrale, a distanza di tre mesi dall'evento acuto sono costretti ad usare la carrozzina. Nel 60% di questi la qualità della deambulazione rimarrà in qualche modo deficitaria rispetto alle necessità richieste da una vita normale (43). Risulta quindi evidente l'importanza di un trattamento intensivo anche per gli arti inferiori, come strumento per ridurre tali numeri.

I Criteri:

I criteri di inclusione ed esclusione sono stati quelli utilizzati per gli arti superiori.

I dispositivi robotici per la riabilitazione degli arti inferiori, emersi da una ricerca analoga a quella effettuati per gli arti superiori, sono i seguenti: Lokomat, Gait Trainer, LokoHelp e G-EOSystems. Data l'esiguità del numero, la strategia di ricerca è stata modificata; in particolare sono stati usati come parole chiave direttamente i nomi propri dei dispositivi, associati nel caso del Lokomat e del Gait Trainer ai termini "rehabilitation" e "randomized trial".

Un' ampio spettro di scale è stato utilizzato per valutare la capacità di deambulazione dei pazienti coinvolti negli studi. In particolare sono state impiegate: Gross Motor Function Measure (GMFM), Functional Ambulation Category (FAC), six minutes walking test (6mWt), the timed 25-foot walk (T25FW), Expanded Disability Status Scale (EDSS), Rivermead Motor Assessment Scale (RMAS), 10-m timed walking speed (10mtws), Motricity Index (MI), Barthel Index (BI), Elderly Mobility Scale (EMS), Modified Motor Assessment Scale (MMAS), Spinal Cord Independence Measurement (SCIM), Functional Independence Measure (FIM).

L'analisi che seguirà sarà suddivisa in base ad ogni singola patologia e, come per gli arti superiori, saranno tenuti in considerazione soprattutto alcuni parametri e scale di valutazione; nel caso specifico saranno considerati: la velocità del cammino, la distanza percorsa, i risultati della FAC, della FIM e del Barthel Index, quest'ultime due intese come scale di disabilità.

I Risultati:

Con l'applicazione di tali criteri sono stati individuati 30 articoli; entrando nel dettaglio 11 riguardavano il dispositivo Gait Trainer, 17 il Lokomat, uno il dispositivo G-EOSystem e uno il LokoHelp. Per ottenere una rieducazione intensiva del cammino agli inizi degli anni '90 è stata introdotto l'impiego del treadmill con supporto parziale del peso corporeo

(BWSTT), tuttavia l'impegno fisico da parte dei fisioterapisti rimaneva alto soprattutto in presenza di importanti deficit motori, e gli studi effettuati non mostravano benefici superiori rispetto alla rieducazione del cammino convenzionale (43). Per questa ragione, successivamente sono stati sviluppati i primi prototipi di robot per gli arti inferiori.

Il primo ad essere introdotto è stato il Gait Trainer (GT1) sviluppato dal gruppo di ricerca del prof. Hesse, seguito dal Lokomat della ditta di Hocoma. Obiettivo di questi dispositivi è una rieducazione intensiva della deambulazione con un minor dispendio di risorse (43).

Dall'analisi degli articoli raccolti, tali robot sono stati impiegati in soggetti affetti da paralisi cerebrali infantili (PCI), sclerosi multipla (SM), traumi spinali (SCI), stroke, sindrome di Brown-Sequard e morbo di Parkinson.

Analogamente a quanto emerso per gli arti superiori i protocolli riabilitativi sono caratterizzati dalla durata del trattamento riabilitativo, dalla frequenza settimanale e dalla durata di ogni singola seduta. Le settimane di trattamento variavano da un minimo di 3 ad un massimo di 28, mentre la frequenza settimanale variava da 2 a 7 sessioni. L'intensità di ogni singolo trattamento del gruppo sperimentale variava da un minimo di 20 minuti ad un massimo di 90 minuti. Diversamente da quanto emerso dall'analisi dei protocolli per gli arti superiori, la durata della sessione riabilitativa del gruppo controllo, quando presente, era sempre uguale a quella del gruppo sperimentale (Tab. V).

Tab. V Tabella riassuntiva delle caratteristiche protocolli riabilitativi con dispositivi robotici dedicati agli arti inferiori

Paralisi Cerebrali Infantili (PCI). Gli articoli individuati riguardanti le PCI sono quattro (44,45,46,47); in tutti gli studi non era presente un gruppo di controllo. Il dispositivo robotico utilizzato era il Lokomat, ad eccezione di un case report dove un solo paziente effettuava il trattamento riabilitativo con il dispositivo Gait Trainer (45). I bambini e gli adolescenti trattati con l'ausilio di Lokomat, mostravano un miglioramento significativo della velocità del cammino e della distanza percorsa; non erano osservati effetti collaterali e tale metodica di trattamento era ben tollerata dai soggetti. Nello studio di Borggraefe (44) un'ulteriore analisi dei risultati in base alla gravità della patologia mostrava che i soggetti con un grado compromissione lieve, rispondevano meglio al trattamento con il Lokomat, rispetto ai soggetti maggiormente compromessi.

Tab. VI La tabella riassume i risultati ottenuti con riabilitazione robot-assistita degli arti inferiori in pazienti affetti da PCI, SCI, SM

Legenda: v: velocità; d: distanza; dea: deambulazione; GMFM: Gross Motor Function Measure; FAC: Functional Ambulation Category; EDSS: Expanded Disability Status Scale; PCI: Paralisi Cerebrali Infantili; SM: Sclerosi Multipla; SCI: Spinal Cord Injury.

Sclerosi Multipla (SM). Per quanto riguarda la SM, sono stati individuati due studi, entrambi con un gruppo di controllo; il trattamento con Lokomat è stato messo a confronto con un training della deambulazione tradizionale e con il tradizionale training con allevio del carico. Negli studi di Lo e Vaney sono stati osservati miglioramenti significativi dei parametri della deambulazione e della disabilità valutata con la scala EDSS, indipendentemente dal trattamento riabilitativo somministrato (48, 49). Da un'ulteriore analisi dei risultati è stato osservato che nel sottogruppo costituito da pazienti con una minore disabilità, il training della deambulazione tradizionale apportava un miglioramento di entità superiore rispetto a quello con robot (49). Nel follow-up a distanza di nove mesi (49) i progressi non venivano mantenuti indipendentemente dal tipo di trattamento effettuato.

Traumi spinali (SCI). Gli articoli riguardanti i pazienti con SCI sono quattro di cui uno è un articolo di review. Tutti gli studi sperimentali erano eseguiti senza gruppo di controllo (50,51,52), utilizzando i dispositivi Lokomat o Gait Trainer, l'impiego di quest'ultimo era associato a stimolazione elettrica funzionale (FES). In particolare i pazienti trattati con Gait Trainer mostravano un miglioramento significativo della velocità del cammino, della resistenza e in caso di paresi di origine centrale, dell'attività del gastrocnemio; mentre i pazienti trattati con Lokomat mostravano un buon recupero del cammino nelle distanze brevi e nella stenia degli arti inferiori. E' stata inoltre ricercata la modalità ottimale di trattamento e dai risultati ottenuti, quella in cui era presente la cooperazione del paziente sembrava risultare la migliore (52).

Nel recente lavoro di review (53) sono stati inclusi studi che impiegavano i dispositivi Lokomat e LokoHelp (due dei quali presi in considerazione anche nella nostra revisione); gli autori ritengono che i miglioramenti osservati siano insufficienti a trarre delle conclusioni definitive, in quanto derivati da studi con una popolazione campione ridotta e spesso eterogenea. Pertanto al momento, il trattamento con dispositivo robotico non può essere considerato superiore a quello convenzionale; gli autori sottolineano quindi la necessità di progettare studi randomizzati controllati (Tab. VI).

Stroke fase acuta/subacuta. Come per gi arti superiori, i risultati saranno suddivisi in fase acuta/subacuta e cronica. Gli studi che coinvolgono pazienti con esiti da ictus recente, sono dieci.

Quattro studi prevedevano l'impiego del dispositivo Lokomat, messo a confronto con un training della deambulazione convenzionale (54,55,56,57). Tali studi mostravano che il training apportava un miglioramento significativo della deambulazione oggettivato dalle

variazioni dei parametri velocità e distanza e supportato dai risultati delle diverse scale cliniche, indipendentemente dal trattamento somministrato. Analoghi risultati erano osservati nelle scale di disabilità.

Ricercando eventuali differenze tra i gruppi di trattamento le conclusioni risultavano spesso discordanti.

Lo studio di Mayr (56) mostrava un miglioramento significativo sia dei parametri della deambulazione che delle scale cliniche nel gruppo di soggetti trattati con Lokomat; al contrario nello studio di Hidler (55) si osservavano variazioni nelle velocità e della distanza percorsa superiori nel gruppo di controllo; tali progressi erano mantenuti anche nel follow-up a distanza di tre mesi. Secondo gli autori questo risultato era imputabile alla variabilità del pattern motorio presente nel trattamento convenzionale che risultava essere più efficace del movimento stereotipato originato dal dispositivo robotico. In un altro studio (57) si rilevava che i soggetti appartenenti al gruppo sperimentale mostravano un aumento della massa magra e un miglior appoggio sull'arto inferiore.

Nei restanti sei studi il dispositivo impiegato era il Gait Trainer. In questo caso il trattamento con robot veniva messo a confronto con fisiochinesiterapia, training della deambulazione e BWSTT talvolta integrato con FES. Nella maggior parte dei casi nel gruppo sperimentale si osservava un miglioramento significativo per quanto riguarda la velocità del cammino, la distanza e il punteggio ottenuto con la scala FAC (58,59,60,61,62). Solo nello studio di Peurala (63) non emergono differenze significative tra i due gruppi trattati, se non per il numero di fisioterapisti impegnati che risulta inferiore quando viene impiegato il dispositivo robotico. All'interno dei diversi gruppi sperimentali l'utilizzo di FES (58,60) non faceva emergere ulteriori differenze significative.

I risultati riguardanti la riduzione di disabilità valutati mediante le scale FIM e BI non risultavano univoci. In due studi (58,60) non si osservava alcun miglioramento significativo, mentre in altri due studi si rilevava una riduzione della disabilità in un caso significativa nel gruppo di pazienti trattati con robot (59,62).

Nel follow-up effettuato a sei mesi di distanza, erano generalmente mantenuti i progressi riguardanti la deambulazione (FAC e velocità), ma non quelli riguardanti la disabilità. (58,59,62).

In questo lavoro sono stati inclusi anche due studi che impiegavano i sistemi LokoHelp e G-EOSystem.

Nello studio con il robot G-EOSystem era valutata l'attivazione dei pattern muscolari durante il cammino e la salita delle scale con e senza robot. Nei due gruppi risultava

un'attivazione muscolare sovrapponibile, indicando in tal modo che tale dispositivo può rappresentare una nuova opportunità terapeutica (64).

Il LokoHelp (65) era impiegato in un gruppo eterogeneo di pazienti affetti da SCI, esiti di trauma cranico e di stroke. In particolare, il gruppo sperimentale era messo a confronto con il training della deambulazione standard o con treadmill. I risultati osservati risultavano significativi nei singoli soggetti senza però produrre differenze statisticamente significative tra i gruppi. L'unica discrepanza individuata era il numero di fisioterapisti impiegati, che risultava inferiore nel gruppo trattato con dispositivo robotico (Tab. VII).

Tab. VII Tabella riassuntiva dei risultati sulla riabilitazione post-stroke robot-assistita degli arti inferiori in fase acuta/subacuta

Legenda: v: velocità, d: distanza percorsa, dea: deambulazione, AC: acuto, SA, subacuto, GR: Gruppo sperimentale con trattamento Robotico; GC: gruppo controllo; fes: stimolazione elettrica funzionale; fkt: fisiokinesiterapia; BWSTT: Body Weight-Supported Treadmill Training; BI: Barthel Index; FIM: Functional Independence Measure.

Stroke fase cronica. Gli studi identificati prevedevano l'impiego dei dispositivi Lokomat o Gait Trainer.

Per il sistema Lokomat i risultati osservati sono discordanti; in due studi (66,67) in cui il training con dispositivo robotico era confrontato con il training della deambulazione tradizionale venivano osservati progressi significativi nel gruppo controllo per la maggior parte dei parametri misurati (velocità, coordinazione cinematica, appoggio su arto paretico). Al contrario quando il trattamento con Lokomat veniva messo a confronto con il BWSTT, il gruppo sperimentale mostrava miglioramenti significativi nella velocità, nella lunghezza del passo e nell'equilibrio (68); nello stesso studio no si evidenziava nessuna differenza per il training effettuato a diverse velocità.

Negli studi con il dispositivo Gait Trainer tutti i pazienti trattati mostravano chiari progressi nella deambulazione, in alcuni casi (69,70) significativi nel gruppo sperimentale; tali guadagni erano mantenuti anche nel follow-up effettuato a distanza di tre e sei mesi (69,71) rispettivamente. La disabilità risultava significativamente ridotta solo in uno studio (69). In particolare, uno studio senza gruppo di controllo (70), evidenziava un pattern elettromiografico più fisiologico nei pazienti trattati con il robot e un miglioramento significativo nella velocità, nella cadenza e lunghezza del passo (Tab. VIII).

Tab. VIII Tabella riassuntiva dei risultati sulla riabilitazione post-stroke robot-assistita degli arti inferiori in fase cronica

Legenda: v: velocità, d: distanza percorsa, dea: deambulazione, CR: cronico, GR: Gruppo sperimentale con trattamento Robotico; GC: gruppo controllo; fes: stimolazione elettrica funzionale; fkt: fisiokinesiterapia; BWSTT: Body Weight-Supported Treadmill Training; BI: Barthel Index; FIM: Functional Independence Measure.

Per quanto riguarda il morbo di Parkinson e la sindrome di Brown-Seuqard, in base ai criteri della ricerca impostati, sono stati individuati solamente due case-report che mostrano progressi incoraggianti, ma data l'esiguità del campione non risultano indicativi (72, 73).

Conclusioni dalla letteratura:

Per quanto riguarda l'utilizzo di dispositivi robotici nel contesto riabilitativo, ad oggi non vi è ancora univocità di pareri su quale sia il contributo globale da essi fornito. L'impatto dei robot sull'autonomia dei pazienti nelle attività di vita quotidiana, anche quando valutato con scale funzionali, non sempre è indicativo di chiari e significativi miglioramenti funzionali.

Più in dettaglio, dall'analisi della letteratura sugli arti superiori emerge che i risultati raggiunti alla fine del trattamento riabilitativo realizzato con robot sono da addurre ad una maggior intensità del trattamento stesso. Come già sottolineato da altri studi, infatti, un miglior recupero motorio si associa ad un alto numero di ripetizioni di esercizi compito-specifici. E' inoltre possibile affermare che l'utilizzo di robot all'interno di un approccio di tipo bilaterale sembra incrementare il recupero funzionale in pazienti con esiti di stroke in misura maggiore rispetto a un approccio unilaterale; alla base di questo trend positivo potrebbe esserci un'attivazione neuronale interemisferica che produce una facilitazione aggiuntiva nel recupero dell'emisfero colpito.

La mancanza di una chiara evidenza di un miglioramento funzionale è da imputarsi prevalentemente al fatto che la maggior parte degli studi riguardano dispositivi di riabilitazione che non includono un training specifico della mano o della funzione di presa ma solamente le articolazioni di spalla e gomito ed in alcuni casi del polso.

Nella riabilitazione degli arti inferiori, si osservano risultati positivi per quanto riguarda il raggiungimento in fase precoce della stazione seduta in carrozzina e successivamente della stazione eretta attraverso l'utilizzo del treadmill con allevio del carico e di altri dispositivi robotici dedicati. Allo stesso modo sono stati riscontrati dati promettenti in merito all'impiego del Gait Trainer nel processo di recupero funzionale del paziente.

Occorre sottolineare che l'analisi della letteratura qui presentata rappresenta un primo tentativo di sintesi coerente sull'argomento, essa va pertanto considerata come un'analisi preliminare del materiale ad oggi disponibile che risulta inevitabilmente soggetto a limiti di carattere metodologico e pratico. Innanzitutto, vi sono questioni metodologiche proprie della ricerca applicata in ambito riabilitativo quali la difficoltà di disegnare e condurre studi

randomizzati controllati (RCT) in grado di fornire evidenze scientifiche certe, la scarsa trasferibilità dei risultati dovuta all' inappropriatezza dei disegni di studio, alla ristretta numerosità e omogeneità dei campioni e infine la presenza di possibili "bias" di osservazione da parte del ricercatore. Numerosi interrogativi limitano poi una piena comprensione dei vantaggi apportati dalle nuove tecnologie in ambito riabilitativo. I fattori critici che dovrebbero interessare clinici e ricercatori in questo campo sono: a) l'effettiva applicabilità di dispositivi tecnologici ai percorsi riabilitativi in uso; b) la pianificazione temporale del programma riabilitativo, con una chiara indicazione sul timing di inserimento delle apparecchiature all'interno del processo riabilitativo; c) l'interazione delle potenzialità dei dispositivi robotici/tecnologici con il profilo funzionale del paziente e l'impatto dell'utilizzo delle tecnologie sull'organizzazione del team riabilitativo cui viene richiesto un training specifico.

Un limite importante dell'impiego dei robot emerso dagli studi è la ridotta variabilità del percorso riabilitativo che risulta vincolato ai criteri di applicazione del dispositivo, un aspetto di rilievo soprattutto se si considera che la maggior parte dei dispositivi ad oggi disponibili è per lo più rivolta al recupero della parte prossimale dell'arto superiore. In futuro sarebbe pertanto auspicabile la progettazione di nuovi dispositivi robotici o l'aggiunta di moduli integrativi a quelli già esistenti da accompagnare ad un uso più estensivo e personalizzato, ed in grado di adattare continuamente il training alle prestazioni ottenute dal paziente durante l'esecuzione dei compiti motori assegnati.

In conclusione, sebbene la riabilitazione robot-assistita non potrà mai sostituirsi al lavoro terapeutico basato sulla relazione e la cooperazione tra paziente e fisioterapista, essa certamente apre nuove e affascinanti prospettive di trattamento dei pazienti che necessitano di trattamenti di neuroriabilitazione, permettendo di intensificare il programma riabilitativo senza dover incrementare i costi e le risorse impiegate.

Tab. I Caratteristiche dei dispositivi robotici dedicati agli arti superiori

Robot	Articolazioni coinvolte			Modalità	Lateralità		
	Prossimal e	Distale	Passiv a			Monolaterale	Bilaterale
ARM guide	X		X	X		X	

ARMin II	X	X	X	X		X	
Bi-Manu		X	X	X	X		X
Track							
GENTLE/S	X		X	X	X	X	
HWARD		X		X		X	
MEMOS	X			X		X	
MIME	X		X	X	X	X	X
MIT-	X	X	X	X	X	X	
MANUS/IMT							
NeReBot	X		X			X	
Reharob	X		X			X	
RehaSlide	X	X	X	X	X		X
Reo Go	X		X	X		X	
TWREX	X	X	X			X	

Durata singola sessione	0-30 minuti	Fino a 60 minuti	Oltre i 60 minuti
Gruppo sperimentale Numero articoli	7	22	3
Gruppo controllo Numero articoli *	11	10	3
Frequenza settimanale	Fino a 3 volte	Da 4 a 6 volte	Quotidiana
Numero articoli	15	13	4
Durata trattamento	Fino a 4 settimane	Fino a 8 settimane	Fino a 12 settimane
Numero articoli	9	19	5

^{*} in 9 articoli non è presente il gruppo controllo

Tab. III Tabella riassuntiva dei risultati sulla riabilitazione post-stroke robot-assistita degli arti superiori in fase acuta/subacuta

Autore	Robot	Protocollo	Variabili	Risultati	Follow- up	Risultati a
			principali		(mesi)	distanza
Hesse,	BiManuTra	Robot vs	F-M,	Miglioramento	3	Mantenuti
2005 (14)	ck	FES	MP/MRC	significativo nel GR		

Lum,	MIME	Robot vs	F-M, MSS	Miglioramento	6	Non mantenuti
2006 (13)		FKT		significativo nel GR		
Aisen,	MITMAN	Robot vs	F-M, MSS,	Miglioramento	_	-
1997 (15)	US	sham	MP/MRC,	significativo della F-M,		
		(spento)	FIM	MP/MRC e FIM in		
				entrambi i gruppi e		
				della MSS nel GR		
Volpe,	MITMAN	Robot vs	F-M, MSS,	Miglioramenti	-	-
2000 (16)	US	sham	MP/MRC,	significativi parziali nel		
		(spento)	FIM	GR		
Rabadi,	MITMAN	Robot vs	F-M, MSS,	Miglioramenti	-	-
2008 (17)	US	ciclo vs TO	FIM	significativi in tutti i		
				gruppi di trattamento		
Krebs,	MITMAN	Robot vs	F-M, MSS,	Miglioramenti	36	Mantenuti
2000 (18)	US	sham	MP/MRC	significativi parziali nel		
				GR		
Masiero,	NeReBot	Robot vs	F-M,	Miglioramenti	3 e 8	Mantenuti
2007 (11)		sham (arto	MP/MRC,	significativi nel GR		(parzialmente a
		sano)	FIM			8 mesi)
Carraro,	NeReBot	Robot vs	MP/MRC	Miglioramento	3 e 8	Mantenuti
2008 (12)		FKT		significativo in entrambi		
				i gruppi		
Hesse,	RehaSlide	Robot vs	F-M,	Miglioramento	3	Mantenuti
2008 (19)		FES	MP/MRC,	significativo in entrambi		
				i gruppi		

Legenda: GR: Gruppo sperimentale con trattamento Robotico; GC: gruppo controllo;

FES: stimolazione elettrica funzionale; FKT: fisiokinesiterapia; TO: Terapia Occupazionale; F-M: Fugl-Meyer Scale, MSS: Motor Status Score; MP: Motor Power;

FIM: Functional Indipendence Measure.

Tab.IV Tabella riassuntiva dei risultati sulla riabilitazione post-stroke robot-assistita degli arti superiori in fase cronica (articoli con GC)

Autore	Robot	Protocollo	Variabil	Risultati	Follow-up	Risultati a
			iprincip		(mesi)	distanza
			ali			
Kahn, 2001	ARMGuide	Robot vs	ChMcM	Miglioramento	-	-
(39)		FKT (robot		significativo in		
		spento)		entrambi i gruppi		
Kahn,2006	ARMGuide	Robot vs	RLA	Miglioramento	6	Mantenuti
(40)		FKT (robot	Test	significativo in		
		spento)		entrambi i gruppi		
Kutner,	HandMento	Robot vs FKT	SIS	Miglioramento	2	Mantenuti
2010 (31)	r			significativo in		(solo ADL)
				entrambi i gruppi		
Takahashi,	HWARD	Robot	F-M	Miglioramento	1	Mantenuti
2008 (21)		(sempre	MP/MR	significativo nel		
		attivo) vs	C	GR		
		robot (attivo				
		per ½ tempo)				
1			1			

Del Conte,	MEMOS	Robot vs FKT	F-M,	Miglioramento	-	-
2009 (10)			MP/MR	significativo nel		
			C	GR		
Burgar,	MIME	Robot vs FKT	F-M,	Miglioramento	-	-
2000 (22)			MP/MR	significativo nel		
			C	GR (solo parte		
			FIM	prossimale); FIM		
				nessun		
				miglioramento		
				significativo		
Lum, 2002	MIME	Robot vs FKT	F-M,	Miglioramento	6	Non mantenuti.
(23)			MP/MR	significativo nel		Miglioramento
			C	GR (solo parte		significativo
			FIM	prossimale); FIM		nella FIM
				nessun		
				miglioramento		
				significativo		
Daly, 2005	MITMANU	Robot vs FES	F-M	Miglioramento	6	Mantenuti
(41)	S	distale		significativo in		
				entrambi i gruppi		
Volpe, 2008	MITMANU	Robot vs FKT	F-M	Miglioramento	3	Mantenuti
(24)	S		MP/MR	significativo in		
			C	entrambi i gruppi		
Lo, 2010	MITMANU	Robot vs FKT	F-M,	Miglioramento	6	Mantenuti nei
(32)	S	intensiva vs	SIS	significativo in tutti		primi due
		"usual care"		e tre i gruppi		gruppi
Fazekas,	REHAROB	Robot vs FKT	F-M,	Miglioramento	-	-
2007 (9)			FIM	significativo in		
				entrambi i gruppi		

Housman,	TWREX	Robot vs FKT	F-M	Miglioramento	6	Mantenuti
2009 (42)				significativo in		
				entrambi i gruppi		
Amirabdolla	GENTLE/S	ABC vs ACB	F-M	Trend positivo nel	-	-
hian, 2007		(A: baseline,		periodo B		
(25);		B: robot, C:				
Coote, 2008		esercizi con				
(26)		arto sospeso)				

Legenda: GR: Gruppo sperimentale con trattamento Robotico; GC: gruppo controllo; FES: stimolazione elettrica funzionale; FKT: fisiocinesiterapia; ChMcM: Chedoke-McMaster Upper Extremity Stroke Assessment Scale; RLA Test: Rancho Los Amigos Functional Test; SIS: Stroke Impact Scale; F-M: Fugl-Meyer Scale, MSS: Motor Status Score; MP: Motor Power; FIM: Functional Indipendence Measure.

Tab. V Tabella riassuntiva delle caratteristiche protocolli riabilitativi con dispositivi robotici dedicati agli arti inferiori

Durata singola sessione	0-30 minuti	Fino a 60 minuti	Oltre i 60 minuti	Non riportato
Numero articoli	12	12	1	5
Frequenza settimanale	Fino a 3 volte	Da 4 a 6 volte	Quotidiana	Non riportato
Numero articoli	8	14	5	3
Durata trattamento	Fino a 4 settimane	Fino a 8 settimane	Oltre le 8 settimane	Non riportato
Numero articoli	14	8	6	2

Tab. VI La tabella riassume i risultati ottenuti con riabilitazione robot-assistita degli arti inferiori in pazienti affetti da PCI, SCI, SM

Autore	Robot	Patologi a	Protocoll o	Variabili principali	Risultati	Follow- up (mesi)	Risultati a distanza
Borggraefe, 2010 (44)	Lokoma t	PCI	Robot	GMFM	Migliorament o significativo	-	-
Meyer, 2009 (46)	Lokoma t	PCI	Robot	GMFM, FAC,	Miglioramenti significativi solo nella GMFM	-	-
Borggraefe, 2010 (47)	Lokoma t	PCI	Robot	GMFM, v, d	Miglioramenti significativi	6	Mantenuti
Farrell, 2010 (45)	Gait Trainer	PCI	Robot	GMFM	Miglioramenti significativi	-	-
Lo, 2008 (48)	Lokoma t	SM	Robot vs BWSTT	EDSS, d	Miglioramenti significativi in entrambi i gruppi	-	-
Vaney, 2009 (49)	Lokoma t	SM	Robot vs training dea standard	V	Miglioramenti significativi in entrambi I gruppi	9	Non mantenuti
Hesse, 2004 (50)	Gait Trainer	SCI	Robot + fes	V	Miglioramenti significativi	-	-
Freivogel, 2009 (65)	LokoHel p	SCI, stroke, traumi	Robot vs treadmill+ training dea standard	FAC	Miglioramenti significativi in entrambi I gruppi	-	-
Manella, 2010 (51)	Lokoma t	SCI	Robot	-	Migliorament o generico della	-	-

					deambulazion e		
Duschau- Wicke, 2010 (52)	Lokoma t	SCI	Robot	-	Valutazione diverse modalità di utilizzo del robot	-	-
Swinnen, 2010 (review) (53)	Lokoma t	SCI	Robot	-	Non evidenza di una superiorità del trattamento con robot rispetto al training dea standard	-	-

Legenda: v: velocità; d: distanza; dea: deambulazione; GMFM: Gross Motor Function Measure; FAC: Functional Ambulation Category; EDSS: Expanded Disability Status Scale; PCI: Paralisi Cerebrali Infantili; SM: Sclerosi Multipla; SCI: Spinal Cord Injury.

Tab. VII Tabella riassuntiva dei risultati sulla riabilitazione post-stroke robot-assistita degli arti inferiori in fase acuta/subacuta

Autore	Robot	Patologi a	Protocoll o	Variabili principali	Risultati	Follow-up (mesi)	Risultati a distanza
Schwartz,	Lokoma	Stroke	Robot vs	FAC, FIM, v	Migliorament	-	-
2009 (54)	t	(SA)	training		o significativo		
			_		della FAC nel		
					GR, della v e		

			dea standard		della FIM in entrambi in gruppi		
Hidler, 2009 (55)	Lokoma t	Stroke (SA)	Robot vs training dea standard	FAC, v, d	Migliorament o significativo della FAC in entrambi i gruppi, della v e d nel GC	3	Mantenuti
Mayr, 2007 (56)	Lokoma t	Stroke (SA)	Robot vs training dea standard	V, d	Migliorament o significativo nel GR	-	-
Huseman n 2007 (57)	Lokoma t	Stroke (AC)	Robot vs training dea standard	FAC, v, d, BI	Migliorament o significativo in entrambi i gruppi	-	-
Peurala, 2009 (63)	Gait Trainer	Stroke (AC)	Robot vs training dea standard vs fkt standard	FAC, v, d	Migliorament o significativi nei primi due gruppi	6	Mantenuti
Ng, 2008 (58)	Gait Trainer	Stroke (SA)	Robot vs robot + fes vs training dea standard	FAC, v, FIM, BI	Migliorament o significativo della FAC e v nei due GR. Nessun migliorament o significativo nella FIM e nel BI	6	Mantenuti
Pohl, 2007 (59)	Gait Trainer	Stroke (SA)	Robot + fkt vs fkt standard	FAC, v, BI	Miglioramenti significativi nel GR	6	Mantenuti FAC e v, Non mantenuti nel BI
Tong, 2006 (60)	Gait Trainer	Stroke (SA)	Robot vs robot + fes vs training dea standard	FAC, v, FIM, BI	Migliorament o significativo della FAC e v nei due GR. Nessun migliorament o significativo	-	-

					nella FIM e nel BI		
Werner, 2002 (61)	Gait Trainer	Stroke (SA)	Robot vs BWSTT	FAC, v	Migliorament o significativo della FAC nel GR e della <i>v</i> in entrambi i gruppi	6	Mantenuti
Bragoni, 2008 (62)	Gait Trainer	Stroke (SA)	Robot vs training dea standard	FAC, BI	Migliorament o significativo della FAC nel GR e del BI in entrambi i gruppi	-	-
Hesse, 2010 (64)	G-EO System	Stroke (SA)	Robot vs senza robot	Valutazione attivazione pattern muscolari	Attivazione sovrapponibil e nei due gruppi	-	-

Legenda: v: velocità, d: distanza percorsa, dea: deambulazione, AC: acuto, SA, subacuto, GR: Gruppo sperimentale con trattamento Robotico; GC: gruppo controllo; fes: stimolazione elettrica funzionale; fkt: fisiokinesiterapia; BWSTT: Body Weight-Supported Treadmill Training; BI: Barthel Index; FIM: Functional Independence Measure.

Tab. VIII Tabella riassuntiva dei risultati sulla riabilitazione post-stroke robot-assistita degli arti inferiori in fase cronica

Autore	Robot	Patologia	Protocollo	Variabili principali	Risultati	Follow-up (mesi)	Risultati a distanza
Westlake, 2009 (68)	Lokomat	Stroke (CR)	Robot vs BWSTT	V, d	Miglioramento significativo della <i>v</i> nel GR e della <i>d</i> in entrambi i gruppi	-	-
Hornby, 2008 (66)	Lokomat	Stroke (CR)	Robot vs training dea standard	V	Miglioramento significativo nel GC	-	-
Lewek, 2009 (67)	Lokomat	Stroke (CR)	Robot vs training dea standard	V	Miglioramento significativo nel GC	-	-

Dias, 2007 (69)	Gait Trainer	Stroke (CR)	Robot vs fkt standard	V, d, BI	Miglioramento significativo della v nel GR e della d in entrambi i gruppi. Nessun miglioramento significativo nel BI.	3	Mantenuti nel GR (migliorame nto significativ o nel BI)
Peurala, 2005 (71)	Gait Trainer	Stroke (CR)	Robot vs robot + fes vs training dea standard	V, d, FIM	Miglioramento significativo della $v e d$ in tutti e tre I gruppi. Nessun miglioramento significativo della FIM.	6	Mantenuti
Hesse, 2001 (70)	Gait Trainer	Stroke (CR)	Robot + fkt standard	v	Miglioramento significativo nel GR	-	-

Legenda: v: velocità, d: distanza percorsa, dea: deambulazione, CR: cronico, GR: Gruppo sperimentale con trattamento Robotico; GC: gruppo controllo; fes: stimolazione elettrica funzionale; fkt: fisiokinesiterapia; BWSTT: Body Weight-Supported Treadmill Training; BI: Barthel Index; FIM: Functional Independence Measure.

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Bibliografia

- [1] <u>Hesse S</u>, <u>Schmidt H</u>, <u>Werner C</u>, <u>Bardeleben A</u>. Upper and lower extremity robotic devices for rehabilitation and for studying motor control. <u>Curr Opin Neurol.</u> 2003 Dec;16(6):705-10.
- [2] R. Colombo, F. Pisano, S. Micera, A. Mazzone, C. Delconte, M.C. Carrozza, et al. "Assessing mechanisms of recovery during robot-aided neurorehabilitation of the upper limb," Neurorehabilitation and Neural Repair, vol. 22, Feb. 2008, pagg. 50-63.
- [3] <u>Kwakkel G, Kollen BJ, Krebs HI</u>. Effects of robot-assisted therapy on upper limb recovery after stroke: a systematic review. <u>Neurorehabil Neural Repair.</u> 2008 Mar-Apr;22(2):111-21.
- [4] R. J. Nudo, "Adaptive plasticity in motor cortex: implications for rehabilitation after brain injury," J Rehabil Med, 41 Suppl, pp. 7-10, May 2003.
- [5] M. Lotze, C. Braun, N. Birbaumer, S. Anders and L. G. Cohen, "Motor learning elicited by voluntary drive," Brain, vol. 126, no. 4, pp. 866-72, Apr 2003.
- [6] Prange GB, Jannink MJ, Groothuis-Oudshoorn CG, Hermens HJ, Ijzerman MJ. <u>Systematic</u> review of the effect of robot-aided therapy on recovery of the hemiparetic arm after <u>stroke</u>. J Rehabil Res Dev. 2006 Mar-Apr;43(2):171-84.
- [7] Mehrholz J, Platz T, Kugler J, Pohl M. <u>Electromechanical and robot-assisted arm training for improving arm function and activities of daily living after stroke.</u> Cochrane Database Syst Rev. 2008 Oct 8;(4).
- [8] <u>Oujamaa L</u>, <u>Relave I</u>, <u>Froger J</u>, <u>Mottet D</u>, <u>Pelissier JY</u>. Rehabilitation of arm function after stroke. Literature review. <u>Ann Phys Rehabil Med.</u> 2009 Apr;52(3):269-93.
- [9] Fazekas G, Horvath M, Troznai T, Toth A. Robot-mediated upper limb physiotherapy for patients with spastic hemiparesis: a preliminary study. J Rehabil Med. 2007 Sep;39(7):580-2.

- [10] C. Delconte, F. Pisano, M.A. Tommasi, A. Cavalli, D. Pianca, A. Mazzone, G Minuco, R. Colombo. La robotica in riabilitazione. G Ital Med Lav Erg 2009; 31:1, 115-123.
- [11] <u>Masiero S</u>, <u>Celia A</u>, <u>Rosati G</u>, <u>Armani M</u>. Robotic-assisted rehabilitation of the upper limb after acute stroke. <u>Arch Phys Med Rehabil.</u> 2007 Feb;88(2):142-9.
- [12] E.Carraro, S.Masiero, G. Rosati, C. Ferraro. Recupero della forza muscolare dopo precoce
- mobilizzazione passiva nel paziente emiplegico. Eur Med Phys 2008;44 (Suppl 1 to No.3)
- [13] Lum PS, Burgar CG, Van der Loos M, Shor PC, Majmumdar M, Yap R. MIME robotic device for upper-limb neurorehabilitation in subacute stroke subjects: a follow-up study. J Rehabil Res Dev. 2006;43:631-642.
- [14] Hesse S, Werner C, Pohl M, Rueckriem S, Mehrhoz J, Lingnau ML. Computerized arm training improves the motor control of the severely affected arm after stoke. Stroke. 2005;36:1960-1966.
- [15] Aisen ML, Krebs HI, Hogan N, McDowel F, Volpe BT. The effect of robot-assisted therapy and rehabilitative training on motor recovery following stroke. Arch Neurol. 1997;54:443-446.
- [16] Volpe BT, Krebs HI, Hogan N, Edelstein L, Diels C, Aisen ML. A novel approach to stroke rehabilitation: robot-aided sensorimotor stimulation. Neurology. 2000;54:1938-1944.
- [17] Rabadi M, Galgano M, Lynch D, Akerman M, Lesser M, Volpe B. <u>A pilot study of activity-based therapy in the arm motor recovery post stroke: a randomized controlled trial.</u> Clin Rehabil. 2008 Dec;22(12):1071-82
- [18] Krebs HI, Volpe BT, Aisen ML, Hogan N. Increasing productivity and quality of care: Robot-aided neuro-rehabilitation. J Rehabil Res Dev. 2000;37(6):639–52.
- [19] Hesse S, Werner C, Pohl M, Mehrholz J, Puzich U, Krebs HI. <u>Mechanical arm trainer for the treatment of the severely affected arm after a stroke: a single-blinded randomized trial in two centers</u>. Am J Phys Med Rehabil. 2008 Oct;87(10):779-88.
- [20] Lin KC, Chen YA, Chen CL, Wu CY, Chang YF. The effects of bilateral arm training on motor control and

functional performance in chronic stroke: a randomized controlled study. <u>Neurorehabil Neural Repair.</u> 2010

Jan;24(1):42-51.

- [21] Takahashi CD, Der-Yeghiaian L, Le V, Motiwala RR, Cramer SC. Robot-based hand motor therapy after stroke. Brain. 2008 Feb;131(Pt 2):425-37.
- [22] Burgar CG, Lum PS, Shor PC, Van der Loos HFM. Developmentof robots for rehabilitation therapy: the Palo Alto VA/Stanford experience. J Rehabil Res Dev. 2000;37:663-673.

- [23] Lum PS, Burgar CG, Shor PC, Majmundar M, Van der Loos M. Robot-assisted movement training compared with conventional therapy techniques for the rehabilitation of upper-limb motor function after stroke. Arch. Phys Med Rehabil. 2002;83(7):952-959.
- [24] Volpe BT, Lynch D, Rykman-Berland A, Ferraro M, Galgano M, Hogan N, Krebs HI. Intensive sensorimotor arm training mediated by therapist or robot improves
 hemiparesis in patients with chronic stroke. Neurorehabil Neural Repair. 2008 May-Jun;22(3):305-10.
- [25] Amirabdollahian F, Loureiro R, Gradwell E, Collin C, Harwin W, Johnson G. <u>Multivariate</u> analysis of the Fugl-Meyer outcome measures assessing the effectiveness of GENTLE/S robot-mediated stroke therapy. J Neuroeng Rehabil. 2007 Feb 19;4:4.
- [26] Coote S, Murphy B, Harwin W, Stokes E. <u>The effect of the GENTLE/s robot-mediated therapy system on arm function after stroke</u>. Clin Rehabil. 2008 May;22(5):395-405.
- [27] Stefan Hesse, MD, Gotthard Schulte-Tigges, PhD, Matthias Konrad, MD, Anita Bardeleben, MA, Cordula Werner, MA. Robot-Assisted Arm Trainer for the Passive and Active Practice of Bilateral Forearm and Wrist Movements in Hemiparetic Subjects. Arch Phys Med Rehabil Vol 84, 2003; 915-921.
- [28] Fasoli SE, Krebs HI, Stein J, Frontera WR, Hughes R, Hogan N. Robotic therapy for chronic motor impairments after stroke: follow-up results. Arch Phys Med Rehabil. 2004;85:1106-1111.
- [29] Fasoli S.E., Krebs H.I., Stein J., Frontera W.R., Hogan N. Effects of robotic therapy on motor impairment and recovery in chronic stroke Archives of Physical Medicine and Rehabilitation 2003 84:4 (477-482).
- [30] Bovolenta F, Goldoni M, Clerici P, Agosti M, Franceschini M. Robot therapy for functional recovery of the upper limbs: a pilot study on patients after stroke.

 J Rehabil Med. 2009 Nov;41(12):971-5.
- [31] Kutner NG, Zhang R, Butler AJ, Wolf SL, Alberts JL. <u>Quality-of-life change associated with robotic-assisted therapy to improve hand motor function in patients with subacute stroke: a randomized clinical trial.</u> Phys Ther. 2010 Apr;90(4):493-504.
- [32] <u>Lo AC</u>, <u>Guarino PD</u>, <u>Richards LG</u>, <u>Haselkorn JK</u>, <u>Wittenberg GF</u>, <u>Federman DG</u>, et al. Robot-assisted therapy for long-term upper-limb impairment after stroke. <u>N Engl J Med.</u> 2010 May 13;362(19):1772-83. Epub 2010 Apr 16.
- [33] Ferraro M, Palazzolo JJ, Krol J, Krebs HI, Hogan N, Volpe BT. Robot-aided sensorimotor arm training improves outcome in patients with chronic stroke. Neurology 2003; 61(11):1604-7.
- [34] Staubli P, Nef T, Klamroth-Marganska V, Riener R. <u>Effects of intensive arm training</u> with the rehabilitation robot ARMin II in chronic stroke patients: four single-cases. J Neuroeng Rehabil. 2009 Dec 17;6:46.

- [35] Stein J, Krebs HI, Frontera WR, Fasoli SE, Hughes R, Hogan N. Comparison of two techniques of robot-aided upper limb exercise training after stroke. Am J Phys Med Rehabil. 2004;83(9):720-28.
- [36] Reinkensmeyer DJ, Kahn LE, Averbuch M, McKenna-Cole A, Schmit BD, Rymer WZ. Understanding and treating arm movement impairment after chronic brain injury: progress with the ARM guide. J Rehabil Res Dev. 2000;37(6):653-62.
- [37] Lum PS, Burgar CG, Shor PC. Evidence for improved muscle activation patterns after retraining of reaching movements with the MIME robotic system in subjects with post-stroke hemiparesis. IEEE Trans Neural Syst Rehabil Eng 2004;12(2):186-94.
- [38] R. Colombo, I. Sterpi, A. Mazzone, C. Delconte, G. Minuco, e F. Pisano, "Measuring changes of movement dynamics during robot-aided neurorehabilitation of stroke patients," IEEE Transactions on Neural Systems and Rehabilitation Engineering: A Publication of the IEEE Engineering in Medicine and Biology Society, vol. 18, Feb. 2010, pagg. 75-85.
- [39] Kahn LE, Averbuch M, Rymer WZ, Reinkensmeyer J. Comparison of robot-assisted reaching to free reaching in promoting recovery from chronic stroke. In: Mokhtari M, ed. Integration of Assistive Technology in the Information Age. Amsterdam, The Netherlands: IOS Press; 2001:39-44.
- [40] Kahn LE, Zygman ML, Rymer WZ, Reinkensmeyer D. J. Robotassisted reaching exercise promotes arm movement recovery in chronic hemiparetic stroke: a randomized controlled pilot study. Journal of NeuroEngineering and Rehabilitation. 2006;3;1-13.
- [41] Daly JJ, Hogan N, Perepezko EM, et al. Response to upper-limb robotics and functional neuromuscular stimulation following stroke. J Rehabil Res Dev. 2005;42(6):723-736.
- [42] <u>Housman SJ, Scott KM, Reinkensmeyer DJ</u>. A randomized controlled trial of gravity-supported, computer-enhanced arm exercise for individuals with severe hemiparesis. Neurorehabil Neural Repair. 2009 Jun;23(5):505-14.
- [43] <u>Hesse S</u>, <u>Mehrholz J</u>, <u>Werner C</u>. Robot-assisted upper and lower limb rehabilitation after stroke: walking and arm/hand function. <u>Dtsch Arztebl Int.</u> 2008 May;105(18):330-6.
- [44] Borggraefe I, Schaefer JS, Klaiber M, Dabrowski E, Ammann-Reiffer C, Knecht B, et al. Robotic-assisted treadmill therapy improves walking and standing performance in children and adolescents with cerebral palsy. Eur J Paediatr Neurol. 2010 Nov;14(6):496-502.
- [45] Farrell E, Naber E, Geigle P. <u>Description of a multifaceted rehabilitation</u> program including overground gait training for a child with cerebral palsy: A case report. Physiother Theory Pract. 2010 Jan;26(1):56-61.
- [46] Meyer-Heim A., Ammann-Reiffer C., Schmartz A., Schäfer J., Sennhauser F.H., Heinen F., et al. <u>Improvement of walking abilities after robotic-assisted locomotion training in children with cerebral palsy</u>. Archives of Disease in Childhood 2009 94:8 (615-620)

- [47] Borggraefe I, Kiwull L, Schaefer JS, Koerte I, Blaschek A, Meyer-Heim A, Heinen F. Sustainability of motor performance after robotic-assisted treadmill therapy in children: an open, non-randomized baseline-treatment study. Eur J Phys Rehabil Med. 2010 Jun;46(2):125-31.
- [48] Lo AC, Triche EW. <u>Improving gait in multiple sclerosis using robot-assisted</u>, <u>body weight supported treadmill training</u>. Neurorehabil Neural Repair. 2008 Nov-Dec;22(6):661-71.
- [49] Vaney C., Gattlen B., Hilfiker R. Effects of locomotion training with assistance of a robot-driven gait orthosis in patients with multiple sclerosis: a randomised controlled study. Abstracts Interlaken, 11.–13. Juni 2009.
- [50] Hesse S, Werner C, Bardeleben A. <u>Electromechanical gait training with functional electrical stimulation: case studies in spinal cord injury.</u> Spinal Cord. 2004 Jun;42(6):346-52.
- [51] Manella KJ, Torres J, Field-Fote EC. <u>Restoration of walking function in an individual with chronic complete (AIS A) spinal cord injury.</u> J Rehabil Med. 2010 Sep;42(8):795-8.
- [52] <u>Duschau-Wicke A</u>, <u>Caprez A</u>, <u>Riener R</u>. Patient-cooperative control increases active participation of individuals with SCI during robot-aided gait training. <u>J Neuroeng Rehabil</u>. 2010 Sep 10;7:43.
- [53] Swinnen E, Duerinck S, Baeyens JP, Meeusen R, Kerckhofs E. <u>Effectiveness of robot-assisted</u> gait training in persons with spinal cord injury: a systematic review. J Rehabil Med. 2010 Jun;42(6):520-6. Review.
- [54] Schwartz I, Sajin A, Fisher I, Neeb M, Shochina M, Katz-Leurer M, Meiner Z. <u>The effectiveness of locomotor therapy using robotic-assisted gait training in subacute stroke patients: a randomized controlled trial.</u> PM R. 2009 Jun;1(6):516-23.
- [55] Hidler J, Nichols D, Pelliccio M, Brady K, Campbell DD, Kahn JH, Hornby TG. <u>Multicenter randomized clinical trial evaluating the effectiveness of the Lokomat in subacute stroke</u>. Neurorehabil Neural Repair. 2009 Jan;23(1):5-13.
- [56] Mayr A, Kofler M, Quirbach E, Matzak H, Fröhlich K, Saltuari L. <u>Prospective, blinded, randomized crossover study of gait rehabilitation in stroke patients using the Lokomat gait orthosis.</u> Neurorehabil Neural Repair. 2007 Jul-Aug;21(4):307-14.
- [57] Husemann B, Müller F, Krewer C, Heller S, Koenig E. <u>Effects of locomotion training</u> with assistance of a robot-driven gait orthosis in hemiparetic patients after <u>stroke</u>: a <u>randomized controlled pilot study</u>. Stroke. 2007 Feb;38(2):349-54.
- [58] Ng MF, Tong RK, Li LS. A pilot study of randomized clinical controlled trial of gait training in subacute stroke patients with partial body-weight support

- <u>electromechanical gait trainer and functional electrical stimulation: six-month follow-up.</u> Stroke. 2008 Jan;39(1):154-60.
- [59] Pohl M, Werner C, Holzgraefe M, Kroczek G, Mehrholz J, Wingendorf I, et al. <u>Repetitive</u> <u>locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial</u> (DEutsche GAngtrainerStudie, DEGAS). Clin Rehabil. 2007 Jan;21(1):17-27.
- [60] Tong RK, Ng MF, Li LS. <u>Effectiveness of gait training using an electromechanical gait trainer, with and without functional electric stimulation, in subacute stroke: a randomized controlled trial.</u> Arch Phys Med Rehabil. 2006 Oct;87(10):1298-304.
- [61] Werner C, Von Frankenberg S, Treig T, Konrad M, Hesse S. <u>Treadmill training with partial body weight support and an electromechanical gait trainer for restoration of gait in subacute stroke patients: a randomized crossover study. Stroke. 2002 Dec;33(12):2895-901.</u>
- [62] M. Bragoni, G. Morone, L. Pratesi, P. Coiro, D. De Angelis, V. Venturiero, S. Paolucci. Effetto dell'utilizzo del gait trainer sugli outcomes riabilitativi nei pazienti con stroke in fase subacuta. EUR MED PHYS 2008;44(Suppl. 1 to No. 3).
- [63] Peurala SH, Airaksinen O, Huuskonen P, Jäkälä P, Juhakoski M, Sandell K, et al. Effects of intensive therapy using gait trainer or floor walking exercises early after stroke. J Rehabil Med. 2009 Feb;41(3):166-73.
- [64] Hesse S, Waldner A, Tomelleri C. <u>Innovative gait robot for the repetitive practice of floor walking and stair climbing up and down in stroke patients.</u> J Neuroeng Rehabil. 2010 Jun 28;7:30.
- [65] Freivogel S, Schmalohr D, Mehrholz J. <u>Improved walking ability and reduced</u> therapeutic stress with an electromechanical gait device. J Rehabil Med. 2009 Sep;41(9):734-9.
- [66] Hornby T.G., Campbell D.D., Kahn J.H., Demott T., Moore J.L., Roth H.R. Enhanced gaitrelated improvements after therapist- versus robotic-assisted locomotor training in subjects with chronic stroke: A randomized controlled study Stroke 2008 39:6 (1786-1792)
- [67] Michael D. Lewek, Theresa H. Cruz, Jennifer L. Moore, Heidi R. Roth, Yasin Y. Dhaher and T. George Hornby. Allowing Intralimb Kinematic Variability During Locomotor Training Poststroke Improves Kinematic Consistency: A Subgroup Analysis From a Randomized Clinical Trial. PHYS THER Vol. 89, No. 8, August 2009, pp. 829-839
- [68] Westlake KP, Patten C. <u>Pilot study of Lokomat versus manual-assisted treadmill training for locomotor recovery post-stroke.</u> J Neuroeng Rehabil. 2009 Jun 12;6:18

- [69] Dias D, Laíns J, Pereira A, Nunes R, Caldas J, Amaral C, et al. <u>Can we improve gait skills in chronic hemiplegics? A randomised control trial with gait trainer.</u> Eura Medicophys. 2007 Dec;43(4):499-504
- [70] Hesse S, Werner C, Uhlenbrock D, von Frankenberg S, Bardeleben A, Brandl-Hesse B. <u>An</u> <u>electromechanical gait trainer for restoration of gait in hemiparetic stroke</u> <u>patients: preliminary results.</u> Neurorehabil Neural Repair. 2001;15(1):39-50.
- [71] Peurala SH, Tarkka IM, Pitkänen K, Sivenius J. The effectiveness of body weight-supported gait training and floor walking in patients with chronic stroke. Arch Phys Med Rehabil. 2005 Aug;86(8):1557-64.
- [72] Moreh E, Meiner Z, Neeb M, Hiller N, Schwartz I. <u>Spinal decompression sickness</u> presenting as partial Brown-Sequard syndrome and treated with robotic-assisted bodyweight support treadmill training. J Rehabil Med. 2009 Jan;41(1):88-9.
- [73] <u>Ustinova K</u>, <u>Chernikova L</u>, <u>Bilimenko A</u>, <u>Telenkov A</u>, <u>Epstein N</u>. Effect of robotic locomotor training in an individual with Parkinson's disease: a case report. <u>Disabil Rehabil Assist Technol.</u> 2010 Jul 28.











