ReAbility: Complex External Prosthesis Systems to Rehabilitate Movement

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Abstract The *ReAbility* Project is a solution that provides an alternative to wheelchair mobility for people with serious disabilities of the lower limbs, such as paraplegics, allowing them to stand and walk once again. This solution is achieved by utilizing an instrument called an "exoskeleton".

The *ReAbility* device is a robotic-assisted system designed to improve the quality of life of people with a movement disability and/or reduced movement; it is meant both for daily domestic use and for rehabilitation therapy in hospitals and rehabilitation centers.

The principal characteristics of the device are its modularity, manageability, and wearability for the patient, who is actively involved and has full control of all the movement functions. Its light weight (16 kg) renders it easy to wear for the patient and competitive on the market. From an esthetic perspective it can be worn under clothes, with obvious and important psychological and social advantages. Its cost is also well contained.

With the use of this device, there is also a very real positive effect on healthcare costs.

Keywords Neurorehabilitation • Exoskeleton • Paraplegy • Spinal cord injury • Movement • *ReAbility* • Healthcare costs

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Introduction

New knowledge has allowed old barriers to be broken. A spinal cord injury has extremely serious consequences for those afflicted, as well as for society in general. People with these injuries often need the help of others in order to conduct their lives, and they face innumerable obstacles along the course of their lives, be it in study, their professions, or other areas. With the right sociopolitical responses, it is, however, possible to enable people with a spinal cord injury to overcome these obstacles in every part of the world and to actively participate in society. Research commitments to paraplegics, in collaboration with the World Health Organization (WHO), are therefore an essential contribution, in their favor, to facilitate self-determination in their daily lives. While it is true that a spinal cord injury changes the life of a person, it is equally true that, notwithstanding this radical change, it is possible to maintain an elevated standard of life and an active daily routine. The WHO report "International Perspectives on Spinal Cord Injury" makes an important contribution in this sense, emphasizing the essential role of science in this pathology. The report presents a summary of the most important scientific factors and the most up-to-date knowledge relevant to the topic of spinal cord injury, offering, in particular, a vision of the fields of epidemiology, sanitary assistance, and medical interventions and an outline of the relevant policies for these conditions. Furthermore, actual experiences in the lives of para- and tetraplegics from across the world are reported. On the basis of this knowledge, concrete recommendations have been made in accordance with the United Nations Declaration on the Rights of Disabled Persons [1].

After the acute phase of a spinal cord injury, it is possible to work on stabilized medullar injuries. In that phase, the *ReAbility* Project has a place.

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The *ReAbility* device is a solution that provides an alternative to wheelchair mobility for people with serious disabilities of the lower limbs, such as paraplegics, allowing them to stand and walk once again. This solution is reached by utilizing an instrument called an "exoskeleton".

The instrument (Fig. 1) is a robotic-assisted system designed to improve the quality of life of people with a movement disability and/or reduced movement, both for daily domestic use and for rehabilitation therapy in hospitals and rehabilitation centers.

The design of the device was made possible by scientific collaboration among international university schools of science and technology, bringing together the world's leading experience on robotics applied to bioengineering.

The *ReAbility* system consists of a wearable exoskeleton integrated with a motor activated in correspondence with the wearer's joints, a series of movement sensors, and an IT system based on sophisticated controls and safe and secure algorithms, as well as a rechargeable battery.

The patient is actively involved and has full control of all the movement functions, through unique control processes. Walking around is controlled by variations in the center of gravity, and stability is guaranteed by the use of crutches.

In detail, the device is a motorized exoskeleton that is worn on the lower limbs either over or under clothes. The electric motors commanding the knee and hip joints, and powered by a battery carried in a backpack on the shoulders, are controlled by a computerized system that is also carried in the backpack. The exoskeleton, designed to be used with two Canadian crutches to guarantee stability, both when walking and when stationary in the erect position, is activated by sensors positioned on the front of the upper body,



Fig. 1 The instrument, a robotic assisted system as a wearable exoskeleton integrated

The device is available in two versions, one for rehabilitation centers, to be used during the rehabilitation treatment, and the other personalized for the patient at the end of the rehabilitation period.

Results

The device allows for multiple results.

From a bioethical and psychological perspective the person is reborn, able to determine their daily life for themselves and dedicate themselves to their preferred activities, and those who are sporty excel, with surprising results.

From a social perspective, a return to socializing and integration between equals is evident.

From a strictly medical point of view, the advantages include regaining the capacity to walk around and the prevention of complications connected to paraplegia (in particular, rehospitalization, bedsores, osteoporosis and consequent pathological fractures and muscular atrophy, spasms, and chronic pain), not to mention a net reduction in the percentage of patients abandoning their classic braces (currently between 15 and 71%).

From an economic aspect, there are also benefits due to the great reduction in healthcare costs (it is enough to think of the costs of the multidisciplinary treatment needed for difficult wounds such as bedsores, femoral fractures, and daily physiotherapy to reduce spasticity and muscular atrophy). In the United States, the cost of medical and intensive rehabilitative treatment for those with spinal cord injuries is estimated to be ten times that necessary for tumor treatment, six times that of a heart attack and three times that of a stroke. The American Food and Drug Administration (FDA) has, accordingly, approved the principles of the *ReAbility* device technology.

To highlight the enormous potential that this innovation holds, we note that a young paraplegic boy wearing an exoskeleton kicked the first ball (Fig. 2) [2] at the World Football Cup on 12 June 2014 in Sao Paolo, Brazil, thereby symbolically kicking off the great sporting event.

Discussion

Advantages of the Device

We can offer paraplegic patients and those with serious paraparesis the opportunity to discover the sensation of standing and walking once more. In fact the exoskeleton enables peo-



Fig. 2 The first ball that a young paraplegic boy wearing an exoskeleton kicked on 12 June 2014 at the World Football Cup in Sao Paolo, Brazil

ple with disabilities of the lower limbs to reinstate the lost functions, and thereby improve their physical health and quality of life.

The principal characteristics of the device are modularity, manageability, and wearability for the patient. Its light weight (16 kg) renders it easy to wear for the patient without help and makes it competitive on the market. From an esthetic perspective it can be worn under clothes, with obvious and important psychological and social advantages. The instrument is thus innovative, modular, light, flexible, and easy to use. The cost is also well contained.

There is also a very real positive effect on healthcare costs: in fact, on the one hand the device reduces the need for physiotherapy and rehospitalization caused by immobility, which many patients are constricted by, and on the other hand, by maintaining the patient in a vertical position daily, it alleviates many of the problems caused by long-term wheelchair use.

Within the realm of international collaboration, the research team has made their field of competence the modelling of walking and the development of dedicated information communication technology (ICT) applications available to facilitate specialization of the device, which is currently generic, for specific pathologies such as ictus.

Target of the Initiative

The *ReAbility* device is intended for people with a disability of the lower limbs, paraplegia, or serious paraparesis arising from multiple causes; in particular, from spinal cord injuries and spina bifida.

War veterans deserve particular mention. In the film *The Men*, Fred Zinnemann illustrates how these men are left half

men: war veterans, paraplegics condemned to a wheelchair. A stylized and relentless opening scene depicts the action in the battle in which Bud Wilczek suffers a spinal injury and moves his legs for the last time. We see Bud, played by Marlon Brando in his tremendous cinematographic debut, with his sweating face and grimace of pain and dismay, together with the desperate voice describing the scene from beyond, twisting in a rise and fall of irony and torment. Immediately after, seen contorted in a hospital bed, Bud wonders: "I survived. Should I feel lucky?". At that time, disabled war veterans had few prospects in life. It has been reported that the Italian Paralympic Committee has signed an agreement with the Ministry of Defence to introduce sport for disabled military personnel. These soldiers, who have, to date, been confined to military hospitals, have been left alone in their search for a sports club.

The *ReAbility* device could similarly also be used for the aged. It could, in fact, be a resource for patients with serious walking difficulties, which are frequently seen in the aged. Considering the epidemiology of the aged population, the potential in this sector could be of extreme interest.

Estimate of Potential Users

Knowledge of the incidence and prevalence of spinal cord injuries makes it possible to organize prevention programs to sensitize the populations most at risk; for example, in schools, work environments, and domestic environments. Moreover, this information is fundamental for the national and regional planning of the Unipolar Spinal Unit in Italy, an organization that is totally dedicated to spinal cord injury treatment and scientific research in this realm [3].

Traumatic medullary lesions are a condition affecting almost one in every thousand people annually (0.721–0.906 per thousand in the United States; thus, about 40 new cases per million inhabitants per year). In Italy the incidence of spinal cord injury is about 18-20 new cases per year per million inhabitants. In a recent Italian epidemiology study [3] (conducted by GISEM: Gruppo Italiano Studio Epidemiologico Mielolesioni), involving the 37 principal centres dealing with spinal cord injuries, 1014 new cases of spinal cord injury were reported in two years.

The average age of the people affected by medullary lesions varies; 30 % are in the age group from 10 to 40 years, with young adults (between the ages of 16 and 30) being the most affected; however, the average age at trauma has increased since the 1970s, from 28.7 to 39.5 years. About 80 % are men, and the male/female ratio is 4: 1).

The majority of cases are the result of trauma (67.5%), but there is a continual increase in the number of cases that are non-trauma-related (32.5%). Among the causes, road

accidents are the leading problem (42%), followed by falls (27.1%) and violence (15.3%), with a large proportion of cases caused by violence being the result of firearms.

In the United States, non-traumatic medullary lesions account for 39% of all spinal cord injuries. They have an incidence equal to 5–10 new cases for every million inhabitants and are principally the result of primary neoplasms, vascular pathologies, inflammations, infections, and degenerative diseases. The etiology puts degenerative pathologies at 53\%, neoplasms at 25\%, infections at 12\%, and vascular pathologies at 3\% of the cases. The average age at the time of injury is higher than in the case of traumatic injury (around 60 years old), while there are no gender differences and frequently the paralysis is incomplete.(34.1\%), with complete paraplegia at 23\%, incomplete paraplegia at 18.5\%, and complete tetraplegia at 18.3\%.

In Europe, spinal cord injuries are estimated to be principally of a traumatic origin. In northern and central Europe the incidence varies between 9.2 and 20 cases per million inhabitants/year, depending on the country and the study methodologies undertaken. The incidence of traumatic spinal cord injury is diminishing in some countries, such as Sweden, where major investment has been made in preventing road accidents, improving the infrastructure, and reinforcing driver education.

The incidence of traumatic cases in southern European countries is between 8 and 12 cases per million inhabitants/year in Spain and 58 cases per million/year in Portugal, while the total number of spinal cord injuries—traumatic and non-traumatic is between 12 and 20 cases per million inhabitants/year.

In the Mediterranean countries the prevalence of all spinal cord injuries, independent of their cause, is around 350 cases per million inhabitants, with this trend rising as a result of the increased life expectancy of people with spinal cord injuries; in the Nordic countries the estimate of only traumatic injuries is 280 cases per million inhabitants.

In Italy it is estimated that every year there are around 1,800 new cases of paraplegia (mostly the consequence of trauma resulting from road accidents or accidents at work) and there is a paraplegic community of around 80,000 people.

Similar estimates can be made for war veterans and for the aged population.

Estimate of the Direct and Indirect Public

Direct Public

The direct public is represented by paraplegic patients and those with serious paraparesis or serious walking difficulties.

Indirect Public

The indirect public is composed of the whole scientificmedical community, with particular reference to neurologists, neurosurgeons, orthopedic specialists, physiatrists, and rehabilitation therapists, as well as the social, sporting, tourist, and economic-financial sectors.

The Objectives

The objectives of the *ReAbility* Project are to provide those who are confined to a wheelchair with restored psychophysical integrity and freedom.

The Project also aims to promote the adoption of a framework for paraplegia that can equilibrate and harmonize the healthcare, social, organizational, economic, bioethical, psychological, and legal implications of this condition.

The Future

The Medical Role

The doctor is not only a professional provider of technical services, nor a mere unit of production, but rather a protagonist in the process of change in the healthcare system, and the evolution of this figure in society takes on a strategic role in the service of the said society.

The Project Aims

The capacity to walk again, provided by *ReAbility*, is revolutionary in that it has an exceptionally positive impact on the patient and their family, as well as having such an impact on society.

The aim of the Project is to relegate the wheelchair to the attic, entrusting in restored mobility for those who cannot walk. The technology that led to the exoskeleton represents the results of an enormous challenge, together with the great impulse of innovation. This sector is in such expansion that, according to the data in *Nova*, *Sole 24 Ore*, a growth rate of 68% per year is expected in exoskeleton diffusion by the year 2020. This will have a phenomenal impact on the quality of life of disabled people, as well as on healthcare costs.



Fig. 3 Sunrise

Future Developments

The future developments are to be found in the concepts of "extended medicine": the passage from clinical medicine to molecular medicine, the microelectronic evolution, the info-telematic evolution, the "extended hospital", and the "extended doctor".

For sure the exoskeleton is an innovative device letting us go to the future.

"There is no night so long as to prevent the sun to rise again" (Fig. 3).

Conflict of Interest Statement The authors declare that they have no conflict of interest.

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