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Hand grip support for rehabilitation and assistance: from patent to TRL5

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***Abstract*— In the last decades, the continuous increase in the number of the vast cohort of chronic patients that constantly need medical assistance and supervision, and the widespread lack of therapist has brought to an increased interest in the role of medical technologies in rehabilitative programs and assistive scenarios. Current clinical evidence in rehabilitation demonstrates that there is an important and increasing demand for innovative therapeutic solutions to recover the hand functions to prevent patients to need assistance in performing daily life activities. This works describes the pathway from patent to TRL5 of a device to support hand grip actions and interaction with daily life objects. E-KIRO is based on the use of electromagnets, which are able to attach/detach interactive objects equipped with a ferromagnetic plate. Five end-users used the device and scored it with excellent usability based on the System Usability Scale.**

***Index Terms*— electromagnets, hand assistance, hand rehabilitation, activities of daily living.**

I. Introduction

In the last decades, interest in medical technologies increased rapidly, due to the ageing of society, increased ability to treat acute phases of the diseases and shortage of therapists. Research in the biomedical field allowed to improve technologies that are increasingly fundamental in rehabilitation therapy and assistive scenarios. Current clinical evidence in rehabilitation demonstrates that there is an important and increasing demand for innovative therapeutic solutions to recover the hand functions. The most popular hand impairments are consequence of stroke, paralysis, injuries, muscular diseases, or spinal cord injury events. Individuals with hand impairments can have significant limitations in performing activities of daily living (ADLs) [1]. In fact, although the impact on performing ADLs varies depending on the severity of the injury, several researchers have shown that individuals with tetraplegia consider an improved hand and arm function as one of their most relevant priorities [2]. The United Nations Convention on the Rights of Persons with Disabilities [3] underlines that *"access to appropriate and affordable services, devices and other assistance for disability-related needs"* helps guarantee an adequate standard of living and social protection to disabled people. The same document also reminds the importance that assistance and rehabilitative tools have in *"enabling persons with disabilities to attain and maintain maximum independence, full physical, mental, social and vocational ability, and full inclusion and participation in all aspects of life"*.

The purpose of this work was to conceptualize, design and produce a hand grip assistance module that could be used in the rehabilitation of the motor function of the upper limb or as an assistive tool for a wide range of patients suffering from hand weakness. Depending on the nature of their impairment, potential end-user could benefit from such device in different ways. For people affected by pathologies involving chronic disabilities (e.g., quadriplegia or advanced muscular dystrophy) the device would act as an assistive technology. Considering only Italian data, about 70.000 people have a spinal cord injury two-thirds of whom are under 60 years of age [4], and muscular dystrophy has an incidence of 20.000 patients (year 2019), often young people and adolescents to whom the disease can cause a progressive muscle weakness [5]. These numbers give a perception of the potential impact of this device. Moreover, the relatively young age of this population suggests that the device could provide them assistance during daily activities for a considerable number of years. A different destination of use is intended for people affected by neuromotor impairment, with particular focus on stroke [6], for whom the device could also serve as a tool in rehabilitation. It is estimated that by 2030, stroke will be the fourth leading cause of disability in Western countries [7]. Considering a period of three months after the acute event, a high percentage of patients do not recover full functionality in relation to their age and these residual alterations concern for 93% the function of the upper limb [8]. Within the rehabilitation phase, the patient could benefit from the grip assistance module, e.g. in occupational therapy. Indeed the device would enable the interaction with everyday objects even if the patient does not have enough residual force to grasp/carry them. As the level of autonomy regained by the patient increases, the mechanical effort level of the grip assist support can be reduced, allowing the patient a gradual recovery, proportionate to the progressive regaining of strength. The population who could benefit from the described approach is not limited to people who have suffered a stroke but also to a broader population affected by peripheral damage to the hand (e.g. patients who have undergone specific surgical operations on the hand). The rehabilitation and assistance to hand functions might be useful in different contexts such as hospitals, specialized facilities for post-traumatic rehabilitation, healthcare residences or even at home.

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II. Aim of the Work

The objective of this work is to provide patients suffering from hand mobility dysfunctions with e-KIRO , a device both for the rehabilitation and assistance of the hand towards independence in performing key ADLs, such as drinking, eating, bathing, communicating, and using electronic devices. E-KIRO might be intended as an assistive device, given that it might be used to increase, maintain, or improve functional capabilities of individuals with disabilities, and as a rehabilitative tool, given that it might be used as a support to recover or improve functions after injury or illness [9], [10]. In the latter context, e-KIRO could support patients who have not enough residual force in handling everyday objects during occupational therapy, configuring itself as a support to the rehabilitative process [10].

III. Related works

Existing solutions for the rehabilitation and/or assistance of hand grip functions might be clustered in two categories. Wearable devices for the rehabilitation of the hand and digits of neurological patients are intended as shared devices between a group of patients, which are used during a rehabilitation/training session. Commercial products examples include Gloreha [11], CarbonHand [12], Rapael Smart Glove [13], CyberGrasp [14] or the Hand of Hope [15]. The characteristic feature of these devices is the high technological and robotic component, which makes them particularly efficient from the point of view of use, but costly and therefore mainly available in dedicated rehabilitation facilities. The robotic solutions usually present (i) the possibility to control the phase of attachment/detachment of the object remotely or through voice control, and (ii) the possibility to modulate the support force exerted by the device. However, these features come with an increase in costs. Moreover, the design of these devices is often less appealing and does not always allow the patient to have direct physical contact with the object to be gripped. On the other side, assistive devices are objects that can be used by patients at home, with the aim of continuous support in carrying out ADLs. Some of the examples include Tactee [16], a permanent magnet-based device to hook magnetic objects. In this kind of device the magnets, of varying sizes, are applied on one side to the assistive device, and on the other side to the object that is to be gripped. The simplicity and effectiveness of these tools make them available on the market at relatively low prices, thus making them accessible to a wide range of patients. In addition, the possibility to use magnets of even very small sizes (specially to perform most ADLs), allows for aesthetically pleasing designs with reduced dimensions. However, permanent magnet-only devices present numerous drawbacks for patient use. Indeed, the gripping/detaching phase of the object cannot be controlled remotely. This implies that if the patient's motor function is not preserved for at least one hand, the independence to use the device is significantly reduced. Moreover, this solution limits the maximum attracting force of the device and, thus, the maximum weight of the object that can be gripped. Indeed, increasing the magnetic force would make the detachment too difficult for users suffering from a high degree of motor impairment. Moreover, these devices are mainly adapted to a purely assistive function and not to a rehabilitative one, as the grip support provided to the patient has constant strength and cannot be changed. Lastly, in many cases, these assistive devices adopt the philosophy of 'one size fits all' and do not accommodate for the individual user. This lack of possible personalization can result in user dissatisfaction. Several other prototypes are described in the literature, including for example Robotic Sixth Finger. [17], Supernumerary Robotic Finger [18], or Vanderbilt hand exoskeleton [19].

The goal of the project was to conceive, design and produce a device that could fill the gaps that devices already on the market and in the scientific literature have. The following targets have been set.

- (i) The device had to be used effectively by the widest possible spectrum of patients both for rehabilitation and assistance purposes. Consequently, designs that were too constraining, such as gloves or thumb restraints, were excluded, given the variety of possible deformations present in patients' hands.
- (ii) The device had to provide, for rehabilitation purposes, a decreasing degree of force exerted by the device according to the patient's regained capacities and, in case of assistive purposes, a constant supportive force for better coping with ADLs.
- (iii) The device had to have a design that allowed direct contact with the object. Many studies show the effectiveness that tactile contact with the object can have both on the motor recovery of the hand and from the psychological point of view for the patient.
- (iv) The device had to give the possibility to control, remotely or through voice command, the phase of gripping and detachment of the object, so that it could be used also by subjects with impaired hand function for both hands.
- (v) The device has to be possibly used in palmar and dorsal configurations, so to include a broad spectrum as possible of impaired hands, up to the most contracted or spastic ones.

In this paper we describe the development steps of the device, starting from concept formulation up to pilot tests with end-users.

IV. Materials and Methods

A. TRL2: Technology concept formulated

E-KIRO is based on the principle that, when the electrical current flows through a solenoid, it produces a magnetic field. If the magnetic field crosses a ferromagnetic material, the effect is amplified and an attractive force is generated to ensure coupling with other ferromagnetic objects. E-KIRO is based on electromagnets that can attract objects with a coupled ferromagnetic element (Fig. 1). Differently from permanent magnets, the electromagnets allow the detachment of the object once the current is nullified. In addition, by

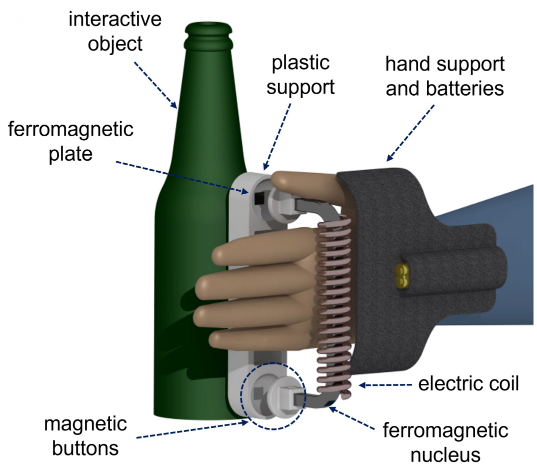

Fig. 1: Rendering of e-KIRO working principle.

changing the current provided, the support can be adapted to different needs (i.e., support only partially the grasped object), exploiting as much as possible user's residual abilities.

B. TRL3: Experimental proof of concept

The e-KIRO hardware is composed by two cylindrical electromagnets, manufactured by Conrad (20mm height, 15mm diameter). When current flows, the electromagnets attract a ferromagnetic plate placed on the interactive object. Both the electromagnets and the ferromagnetic elements are encapsulated in a 3D-printed shell (Fig. 2, panel A). The power supply is provided by commercial rechargeable LiPo batteries (nominal voltage 3.7, maximum operating current 1.5A). The electromagnets are activated through a printed circuit control board, which in turn controls the current delivered to the inductors through a pulse-width modulation (PWM) strategy. The PWM strategy is controlled on 4 levels, starting from the maximum allowed current given by the batteries (i.e. nominal voltage 7.2V). The control unit communicates via a Bluetooth module with a mobile phone application which takes input from the user to drive objects attachment/detachment (Fig. 2, panel B). The user can interact with the device by means of vocal commands or by using specific touch buttons on the mobile phone application.

C. TRL4: Technology validated in lab

E-KIRO has been designed to be compact and lightweight, to allow maximum freedom of movement. To avoid burdening the hand with a cumbersome device, the control board is included in a separate shell that can be secured to the user's arm. The shells of e-KIRO are printed in nylon (PA12) and provided with Velcro straps to ease donning and doffing operations. To validate the device, functional tests included: i) the ability to lift in all directions objects weighing 500gr (i.e., a bottle of water), which has been identified as a target maximal weight for objects handled during common ADLs, ii) the ability to attach objects both in palmar and dorsal configurations. In compliance with EEC 93/42 and MDR EU

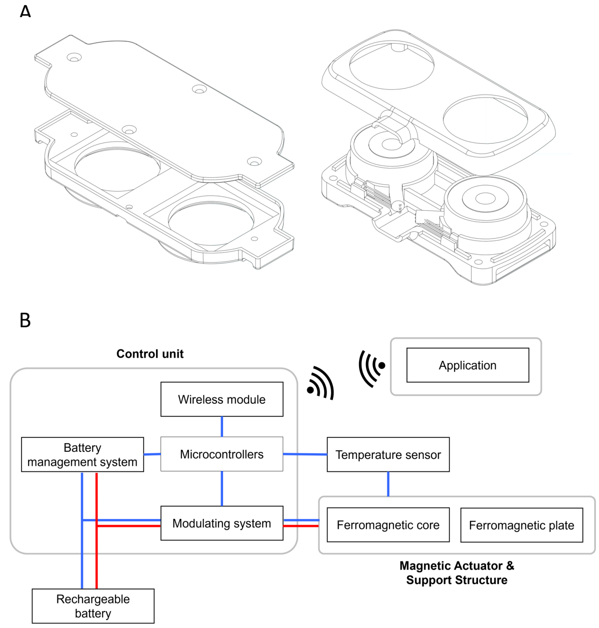

Fig. 2: A) View of e-KIRO CAD model. Left: support of the ferromagnetic element, to be mounted on the interactive object. Right: the electromagnets and their housing, to be secured to the patient's hand. B) Schematic diagram of the e-KIRO prototype with its connections, supply current (red), control signals and data streams (blue).

2017/745 regulations on medical devices, the grip assistance module must be isolated from the user and the external environment. In this regard, thermal insulation is a critical aspect, to avoid the patient feeling hot, due to the Joule effect occurring both in the electromagnets and in the battery. Following standard EN-ISO 13732-1:2009 for temperature of contact surfaces for hot surfaces, the maximum temperature to prevent burning for a hot surface in contact with the skin for 10 minutes is 48°C, and 43°C for a contact up to 8 hours. Therefore the reaching of the thermal plateau has been included as a further test, to verify that the continuous use in the intended maximal current conditions does not reach a temperature harmful to the user's hand.

D. TRL5: Technology validated in relevant environment

E-KIRO has been tested with a pilot group of 5 post-stroke patients at Villa Beretta Rehabilitation Center (Costamasnaga, Italy). Each participant was asked to wear e-KIRO in the preferred configuration (i.e., palmar or dorsal), and to perform the following testing activities.

- Starting from a comfortable resting position, grasping a glass, move it to a different location on the table, and go back to a rest position;
- Starting from a comfortable resting position, grasping a plastic glass, move it towards the mouth to imitate a drinking task, place back the glass on the table, and go back to a rest position.
- Starting from a comfortable resting position, grasping

the knife and the fork (one with e-KIRO and the other one with the health side), cutting a play dough hamburger, and place different pieces in a bowl, place back fork and knife on the table, and go back to a rest position.

All participants were left free to choose how many times to repeat each task and to familiarize with e-KIRO by performing any other desired task. At the end of the training session lasting 30 minutes, we investigated device usability with the System Usability Scale (SUS) [20]. SUS is a ten-items scale for a score between 0 and 100 that provides a global view of subjective assessments of usefulness, as a combination of effectiveness, efficacy, and satisfaction of the system. The global scores were interpreted according to Bangor's guidelines [21].

V. Results

A. TRL2: Patent

The novel technology concept formulated has been submitted and accepted as patent. Patent No: 102017000027918 "Dispositivo per l'assistenza controllata della presa" – Inventors: Pedrocchi A. Foglia G.M. Priority date: 2017-03-14. International PCT Application n. PCT/IB2018/051652, filing date: 2018-03-13, titled: "Device for controlled assistance of the grip".

B. TRL3: Experimental proof of concept

E-KIRO has been produced and tested for its correct functioning in both palmar and dorsal configurations. It has been experimentally verified that, when the electromagnets are provided with the maximum voltage with the PWM strategy, the system ensures the safe gripping of objects with a mass of up to 1 kg in every spatial position, both in palmar and in dorsal configuration. When the voltage provided to the electromagnets is decreased, then the attracting force is pairwise decreased, allowing to fully attract only lower weights. Attracting force between the two ferromagnetic components was effective, and correctly answered to user's inputs. Starting from the formulated concept, prototypes have been developed and tested up to the current version of e-KIRO (Fig. 3).

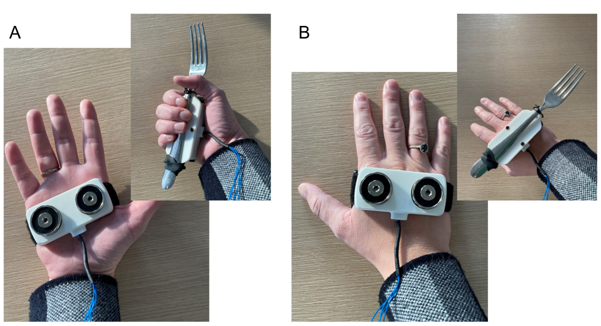

Fig. 3: A) e-KIRO in palmar configuration; B) e-KIRO in dorsal configuration.

Fig. 4: Demo of e-KIRO used in cutlery handling. The control board unit is attached to the user's forearm.

C. TRL4: Technology validated in lab

The element to be secured to the patient's hand (Fig. 3) is 70×34mm and weights 175gr, thus e-KIRO is lightweight and can fit the size of a human hand. Similarly, the control board unit size (175×43×30mm) and weight (≈220gr) allow it to be comfortably worn on the arm (Fig, 4). Concerning the operational performance, e-KIRO proved to be effective in attaching the target weight (i.e. 500gr), regardless of hand orientation and device configuration (i.e. palmar or dorsal). The control unit of the prototype has been designed to guarantee continuous working with maximum attracting force for 8 hours. The thermal plateau has been reached after 15 minutes of continuous use at maximum current (i.e. i=167mA), reaching 41°C at magnets level. The same results about the maximum temperature have been confirmed after 6 hours of continuous use. As the maximum allowed temperature at skin level is 43°C, and as magnets are insulated from the skin by the PA12 case, the experimental set-up has been considered safe for the intended use. Nevertheless, temperature sensors have been included in contact with both the electromagnets to continuously monitor the current. An alarm is triggered when the internal temperature reaches 40°C, and, if the temperature reaches 43°C, the current is turned off.

D. TRL5: Technology validated in relevant environment

Participants' characteristics are summarized in Table I. Depending on their residual dexterity, some of the participants donned e-KIRO autonomously, while others required assistance during the operation. In both cases, donning and doffing the device required less than 1 minute. Figure 5 shows e-KIRO used by two participants when performing simple actions during training.

Considering the SUS scale, across all patients, the mean SUS resulted to be of 87 points (max 97.5, min 75), which can be interpreted as "excellent", and well overcoming the threshold defined by Sauro (i.e., 68 points) [22].

VI. Discussion

Partially regaining a lost ability is a special experience for an impaired person. A lot more might be done on the technological side to support rehabilitation and assistance

	S01	S02	S03	S04	S05
Age	72	64	72	54	55
Sex	F	M	F	M	M
Side of hemiparesis	L	R	L	L	L
MRC index of hand flexor muscles	4	0	3	5	3
MRC index of hand extensor muscles	4	0	3	5	3
Configuration	Palmar	Dorsal	Dorsal	Palmar /dorsal	Palmar

TABLE I: Demographic characteristics of pilot end-users.
M Male; *F* Female; *L* Left; *R* Right;
MRC Medical Research Council.

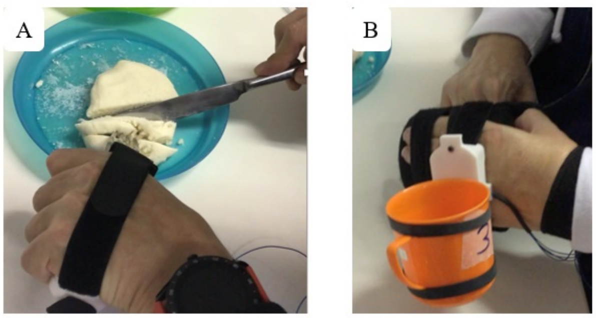

Fig. 5: A) e-KIRO V1 used in palmar configuration; B) e-KIRO V1 used in dorsal configuration.

of hand functions. The goal of this project is to develop, produce and test a simple device to support the interaction with everyday objects, such as a cup, the brush, a bottle of water, the mobile phone. "From the patient's point of view improvement is measured by regaining lost abilities,- by being able to do something –anything- today I couldn't do yesterday" [23].

E-KIRO is an active device based on electromagnets placed on the palmar or dorsal side of the hand of the user, which can attract a ferromagnetic element placed on the target objects. The use of electromagnets allows the user to autonomously decide whether to attach or detach an object. The simple design of e-KIRO enables it to be placed on a broad range of hands, without the constraints derived from the use of gloves. In palmar configuration, e-KIRO allows direct contact with the object, to favour a positive psychological feedback from the patient. Through vocal control, the user might perform bimanual tasks, and it can be used also by subjects with impaired hand function in both hands. E-KIRO might be used in the rehabilitation context with a dual objective. First, e-KIRO might support object's weight during functional movements allowing to interact with real objects even if the patient has not enough residual force to grasp/carry the desired object, e.g. in occupational therapy, where interaction with real objects is critical. Secondly, given the possibility to modulate the electromagnets attracting force, e-KIRO can give support without completely substituting the volitional effort required to the patients, up to turning off the current and leaving the subject to autonomously handle the object. In this view, e-KIRO might be seen as a support to the therapy, particularly in occupational therapy, more than a rehabilitation device itself.

VII. Conclusions

In this contribution, we describe the undertaken steps starting from basic idea and patent up to TRL5. E-KIRO prototype has been successfully tested by a pilot group of end-user in the relevant environment. Usability results are encouraging, showing an excellent usability score, even if only in a pilot group of patients. Further tests with final users are foreseen to fully validate the system, and to verify the hypothesis that e-KIRO may enhance the user's autonomy in ADLs. In the upcoming tests, to have better insight on the user's experience, participants will be asked to evaluate e-KIRO not only using the SUS, but also through other dedicated questionnaires. A possible improvement for e-KIRO could be to autonomously adapt the exerted force depending on the user's residual ability. In this view, the integration of slip sensors will be considered to control the current flow to the electromagnets. Finally, it should be noted that, to date, most of the effort have been made to develop the functional aspects of the device. Toward the actual deployment of e-KIRO , a part of the process will be devoted to verify the compliance with the relevant regulations.

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