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► **To cite this version:**

Marco Ceccarelli, Matteo Bottin, Matteo Russo, Giulio Rosati, Med Amine Laribi, et al.. Requirements and Solutions for Motion Limb Assistance of COVID-19 Patients. *Robotics*, 2022, 11 (2), pp.45. 10.3390/robotics11020045 . hal-03830827

HAL Id: hal-03830827

<https://hal.science/hal-03830827>

Submitted on 17 Oct 2023

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Article

Requirements and Solutions for Motion Limb Assistance of COVID-19 Patients

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Abstract: COVID-19 patients are strongly affected in terms of limb motion when imbedded during the acute phase of the infection, but also during the course of recovery therapies. Peculiarities are investigated for design requirements for medical devices in limb motion assistance for those patients. Solutions are analyzed from existing medical devices to outline open issues to provide guidelines for the proper adaption or for new designs supporting patients against COVID-19 effects. Examples are reported from authors' activities with cable driven assisting devices.

Keywords: COVID-19; limb biomechanics; medical devices; limb motion assistance; survey



Citation: Ceccarelli, M.; Bottin, M.; Russo, M.; Rosati, G.; Laribi, M.A.; Petuya, V. Requirements and Solutions for Motion Limb Assistance of COVID-19 Patients. *Robotics* **2022**, *11*, 45. <https://doi.org/10.3390/robotics11020045>

Academic Editor: Naira Hovakimyan

Received: 27 January 2022

Accepted: 1 April 2022

Published: 4 April 2022

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1. Introduction

During the COVID-19 pandemic, hospitals have faced an elevated number of patients being constrained in bed due to infection. As a result, many of them have faced weakness and decreased motion capacity due to cardiopulmonary dysfunction as well as the muscle atrophy caused by long-term immobilization of the most severe cases.

In such cases, there is a need both for exercise during hospitalization, so as not to reduce muscle functionality, and rehabilitation, to recover muscle functionality if the former is not possible. Unfortunately, due to pandemic-related containment measures, isolation from support networks may exacerbate difficulties to apply rehabilitation programs for patients as they recover from COVID-19, even in the acute phase, both in a home environment as well as in a hospital setting. As a result, there is a need for new devices to support health-care operators in the management of the action and clinical medical monitoring in motor exercise, promoting and optimizing functional independence in activities of daily living.

In this paper, a survey on the existing medical devices to be used specifically for limb rehabilitation is carried out, similarly to what has already been published for medical robots deployed for prevention, screening, diagnosis, treatment, and home care [1]. Firstly, the effects of COVID-19 on limb motion capabilities are described. Secondly, the problem and requirements related to limb rehabilitation are outlined. Then, existing medical devices are discussed. Finally, guidelines for updated or new solutions are provided, with an example from the authors' direct experience.

2. Effects of COVID-19 in Limb Motion Capabilities

Even if most of the common symptoms of COVID-19 acute infections are not directly related to muscular atrophy [2,3], in some cases weakness has been recorded [4], and, above all, skeletal muscles seem to be affected by the acute syndrome (SARS-CoV-2) [5,6]. Moreover, in some cases, if productive cough is a symptom [7], physiotherapy may be indicated [8].

An extended period spent in the hospital can result in muscular distress [9], especially for the most severe patients who may have been confined in bed due to required mechanical ventilation, even for several weeks [10]. As a result, it is also convenient to maintain motion activity during the hospitalization period. A continuous rehabilitation and exercising process is then required, which is not only needed for the physical rehabilitation, but also to avoid cognitive and emotional complications, as recorded in post intensive care syndrome (PICS) [4]. Indeed, Menges et al. [11] have shown that it is crucial to start the mobilization as soon as possible to speed functionality recovery.

The effects of COVID-19 on the muscles have been studied in the last year. Ali and Kunugi [12] studied the possible mechanisms of muscle damage and the long-term consequences of muscle injury. In particular, participants who were hospitalized for three weeks, even after two or three months back home, showed poor health-related quality of life, also related to the loss of weight and muscular mass. This result is further confirmed by Medrinal et al. [13], who studied the data from 23 patients and found that 44% of them were unable to walk 100 m 30 days post-discharge. Those authors have stated again the importance of the rehabilitation treatments during and after ICU.

3. Problems and Requirements

Motion exercise and rehabilitation during the COVID-19 pandemic are opposed by the containment measures during medical treatments. Most of the time, post-care patients who have returned home are required to perform physical exercises on their own, which is shown to be crucial to improve physical fitness [14]. Not only can weakness due to PICS be enough to reduce the willingness of a patient, but it is difficult to perform physical activities even for non-infected people [15].

Thus, it is necessary to help the patients with motion exercise and physical rehabilitation by providing them with proper equipment. Due to the large variety of patients needing rehabilitation (e.g., in terms of age, size, conditions), the equipment must be simple to use, lightweight in order to be carried to different locations, cheap to manufacture, and fairly simple to operate. In this way, a patient can perform exercises or rehabilitation on their own, without the need of a medical operator.

Moreover, the same need is present in the acute hospital setting: if patients are under mechanical ventilation, the exercises may result in circuit disconnections, and non-ventilated patients may cough or expectorate mucus, thus resulting in a potential hazard for the physiotherapists [8]. In this setting, the devices should be for single patient use or, in the case of large equipment, must be easily decontaminated [16]. Application of those devices may also provide support in hospitals where organizational issues are found [17], i.e., when there is a lack of experienced or trained staff.

Physiotherapists have already started providing guidelines for the proper rehabilitation of COVID-19 patients. Examples are provided by Quigley et al. [18] and Thomas et al. [8]: one of the possible solutions is telerehabilitation, but the patients need to be properly equipped. Telerehabilitation is proven to be a good option for the treatment of musculoskeletal conditions and is comparable to standard practice [19].

The effects associated with severe COVID-19 disease may be amplified by underlying health conditions and older age. Weakness and decreased exercise capacity are the most common symptoms and dysfunction. The causes of weakness can be attributed to the decline of exercise endurance associated with cardiopulmonary dysfunction, and to the muscle atrophy caused by long-term immobilization in severe patients. Isolation from support networks as a result of pandemic-related containment measures may exacerbate

difficulties to apply rehabilitation programs for patients as they recover from COVID-19. Rehabilitation after serious illness is an important activity in the continuum of care. It requires complex actions with a long process that is aimed at minimizing the disabling effects of impairments, recovering functional independence in daily activities, and promoting capabilities to participate again meaningfully in society. Rehabilitation and motion exercise is also useful from a medical point of view for the general clinical state of a COVID patient and therefore requires a suitable activation, which can be performed using the mechanical interface modules in the parts of the body available for this exercise. The mechanical interfaces may consist of rings that can be worn and inflated for a suitable anchorage in the required parts of the body with sensors and actuators, which allow their relative mobility in motion assistance in the part of the involved body. A particular aspect of the application of those devices is related to the sterility of the parts, especially those in contact with a COVID patient, requiring an adequate support system for sterilization after each application of motion assistance.

Figure 1 summarizes the aspects that should be considered for the suitable design and operation of motion assistance for limbs, with some specific requirements coming from the specific condition of COVID-19 disease by considering the two different perspectives of user-patient and medical operator/physiotherapist, respectively.

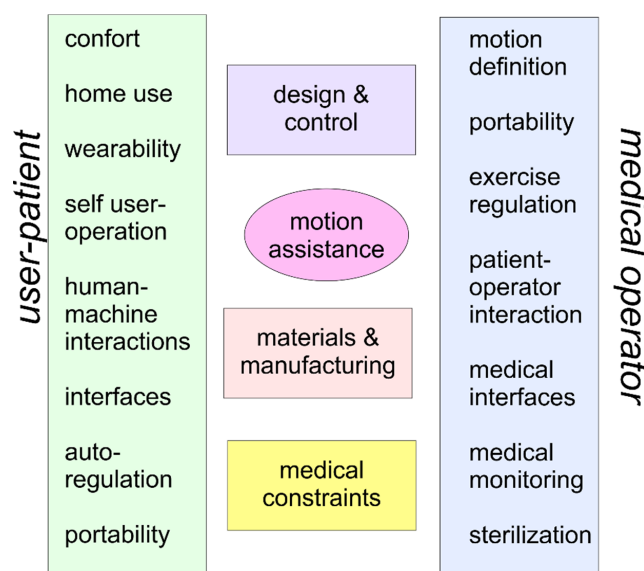


Figure 1. Aspect for problems and requirements in design and operation of assisting device in limb motion.

As per patient care, attention can be addressed mainly to:

- **Comfort:** User comfort can be considered a requirement with constraints for the functional medical purposes of a motion assistance device, although sometimes it is considered of minor importance. The comfort in weak COVID patients requires specific considerations in terms of the wearing and usage of the device not only for design and functional problems, but even for man-machine interactions and psychological effects on a user.
- **Home use:** A home device presents problems for both the design and operation when a device is conceived to be handled directly by a user in an environment, such as home frames, which are not accommodated for medical devices. Thus, particular attention can be necessary in terms of the sizes, functionalities, and interactivity with a user when considering additional requirements to address medical hygiene and environmental safety.
- **Wearability:** Wearability depends on comfort and the possibility of user autonomy in using a device. It is also a fundamental aspect for user acceptance, and it affects

interactions with the patient's arm, the ease of application, and the use of the device with specific other sensors.

- Self-user operation: Autonomy in operating a motion assistance device is an important characteristic for acceptance and practical usage. This aspect includes learning, training, and handling the operation of the device, including regulation and monitoring during motion exercise.
- Human-machine interactions: The interactions among limbs with their parts and the device determine specific characteristics for motion assistance in terms of requirements and constraints, but they also present specifications for the design and functionality of a device with proper levels for movements and actions of the device connected to the user's limb.
- Interfaces: Interfaces are necessary in terms of device operation for movement adjustments in the user's exercise, and they are also required for motion and clinical monitoring with supervision by medical operators, e.g., via smartphone.
- Auto-regulation: A device can be conveniently designed with intelligent self-regulation in order to operate with proper levels of autonomy for the user's personal safety. The regulation and control of the device operation during motion assistance can be designed with control algorithms that should be developed with functions depending on the user's reactions.
- Safety: User safety is a fundamental aspect for any motion assisting device, such as a machine design interacting with a human body. High-reliability levels and risk awareness are expected both by users and medical operators, following a full understanding of the design and operation of a device.
- Portability: The ease of transportation and setting up of an assisting device can be fundamental for the device to be properly located in a hospital or home frame, as well as for avoiding interference with other assisting equipment.
- As per the medical operator side, attention should be paid to:
- Motion definition: The motion characteristics in the exercise of motion assistance require clinical medical diagnosis of the patient conditions by a medical operator and the possibility of performing motion exercises properly with the device available. The determination of assisted motion requires synergy and integration of the device's motion capabilities with the physiotherapy therapy that is indicated by a medical operator for a specific user-patient.
- Portability: Portability is a fundamental characteristic of motion assisting devices to satisfy the needs of patients and therapy plans established by physiotherapists, as well as to adapt the motion assistance to specific patient constraints and conditions, whether the location of the assistance is in hospital or home frames. The portability feature can also be expressed in terms of light design, easy operation, and easy adaptability to patient anatomy.
- Exercise regulation: Exercise regulation is a key aspect of motion assistance both for users and medical operators according to a prescribed medical therapy. Thus, the regulation and control of the motion exercises will be assisted by suitable sensors that are useful also for monitoring and remote control by a medical supervisor.
- Patient-operator interaction: Interaction between a patient and medical operators during a motion-assisted exercise session can be expected in such a way that a real-time reaction is ensured to give outputs and instructions for necessary adjustments in the exercise, as well as to share data and problems on the exercise results.
- Medical interfaces: Medical interfaces are fundamental equipment components in a motion assisting device with the aim of monitoring and checking clinical and medical parameters during motion exercise sessions. Those medical interfaces, such as sensors and vision systems, can be considered necessary complements when integrated into a device for an interactive operation by users and medical operators.
- Medical monitoring: Medical monitoring and supervision are indispensable for evaluating the effects of motion exercises as well as for permitting the timely indications of

medical operators to a user-patient during and in anticipation of an exercise session. Such medical monitoring equipment can include sensors and medical interfaces as well as special equipment useful for monitoring activity with video transmissions and even remote modes.

- Safety: Safety issues and medical constraints must be taken into account as a first requirement in the usage of motion assisting devices, and even if medical issues cannot be represented with clear technical constraints, they may identify new problems and new solutions in terms of the technical design and medical operation of those devices.
- Sterilization: Sterilization is an essential aspect in dealing with the COVID patients and therefore requires suitable care in terms of design and operation in order to ensure full cleanness with a fairly simple procedure after each use of a device, either by the user-patient alone or by an assistant to the user.

The above-mentioned aspects can be understood as an overview of the open issues and the related problems that will be considered in the development of a technical-medical device useful for motion assistance in rehabilitation, mobility, or exercises. All those aspects, as well as additional ones from specific applications, can form the bases of technical and medical considerations in the process for the design and functionality of a system for motion assistance. Thus, with the above considerations, a device design can satisfy the three types of goals, namely patient benefits, technical sides, and medical applications.

Figure 2 presents a conceptual scheme summarizing how the above problems and requirements can be considered and indeed implemented in a device for limb motion assistance by considering the general aspects, for which the specific attention to COVID disease can be considered a reinforcement of those requirements. In particular, Figure 2 is supposed to express the strong relationship between the device and the medical environment, as with the peculiarities of the COVID disease, may impose on the technical solutions by still considering the patient the center of the device purposes. The unique requirements of those assisting medical devices for COVID-19 patients are discussed by referring to Figures 1 and 2 by indicating the additional problems and requirements for those systems when they should be used by/for COVID-19 patients. Those aspects refer mainly to sanitarian and disinfection issues, telemonitoring capability of the exercising activity, and flexibility for automatic or controlled operation depending on the status of the user-patients.

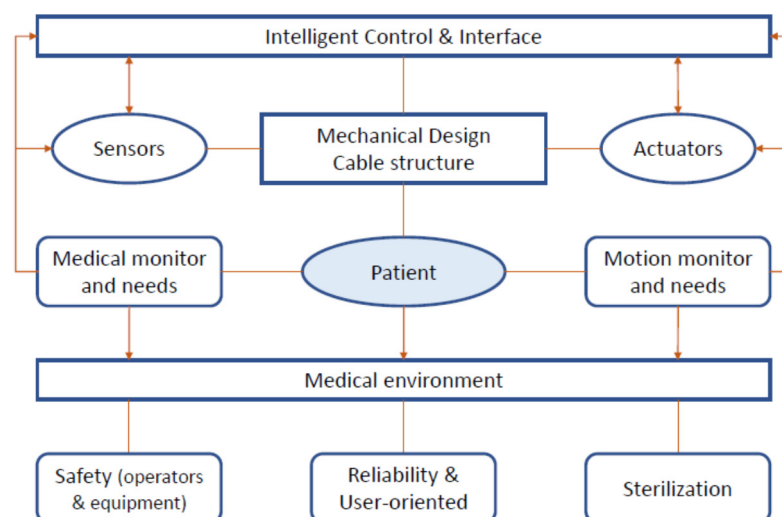


Figure 2. A conceptual scheme for design and operation procedures taking into accounts problems and requirements as in Figure 3.

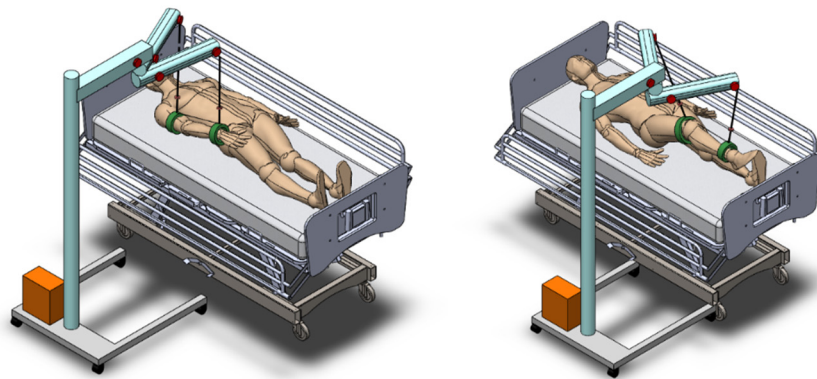


Figure 3. A CAD design for assembling CADEL device with NERI system in limb motion assistance of embed COVID patients.

4. A Survey on Existing Medical Devices

In recent years, several motion assistance devices have been proposed. Such devices, although not designed specifically for the rehabilitation of COVID-19 patients [20], may fulfill this goal [21].

A recent survey on lower-limb exoskeletons is provided by Rodriguez-Fernandez et al. [20]. Most of the proposed devices are actuated by electric motors so that they are suitable for home use. However, not all of them are suitable for a first-action rehabilitation (i.e., during ICU), since their control system provides motion assistance based on tilt sensors. In other words, the control system is triggered by a proactive movement of the patient, and therefore a device cannot be used when the patient is imbedded. An example of such a device is ReWalk [22]. Other devices such as WPAL [23,24] are controlled directly by buttons, so they could be used by a physiotherapist in ICU.

Regarding upper-limb devices, in recent years, different reviews have been published [25,26]. In particular, Maciejasz et al. [26] found and compared more than 120 devices, which means that during the years they have been of great interest. One of the most famous devices is NeReBot [27], which can be used both with imbedded and seated patients. This flexibility is of great importance if the device must be used in different scenarios. However, NeReBot is not suitable for home use due to its encumbrance.

Another assisting device with suitable features can be identified in the NURSE (Cassi-No-Queretaro Upper-Limb Assistive Device), a motion assistance device for upper limbs [28]. The device is designed with a linkage structure that has a large workspace for physical therapy or motion exercising with individuals of any age and size. The NURSE prototype is designed with a structure weighing 2.6 kg with a workspace area of $35 \times 45 \times 30$ cm and operates with characteristics required for successful application in the activity for rehabilitation and exercising of COVID19 patients, mainly during their recovery activity as per its low-cost design and operation, portability, easy user-oriented operation, and easy cleaning after use.

Attention has been paid to medical devices for motion assistance with characteristics and problems of low-cost robotic solutions, [29], which are also discussed in conference forums, e.g., in the ICCOR conference series [30]. Examples of such an activity can be illustrated in the examples in the references [31–33], which report low-cost portable systems for wrist [31], finger [32], and upper limb [33] rehabilitation. However, of these solutions, only finger exoskeletons are truly portable, and thus wearable, whereas the others, while low-cost and lightweight, still require an installation on an appropriate stable structure to be used. Thus, there is still a need to develop new, fully wearable solutions.

The above examples of motion assisting devices can suggest a successful adaptation and combination of existing solutions for application in home and hospital environments by addressing proper design and operation problems coming from the specific requirements

for COVID-19 patients. A suitable system can be designed based on the prototypes of the above-mentioned previously developed solutions in a CADEL (cable driven elbow assisting device) cable device for arm joint rehabilitation and a NERI robot system with cables for arm rehabilitation with tower support, as shown in Figure 3. The system can be defined as an assembly and improvement of the two previous prototypes by providing a single system that can still carry out cable-driven rehabilitation functions of parts of the body of a COVID patient on the intensive care bed without any reactivity, and for COVID patients in sub intensive care, up to even home recovery with self-exercising.

It must be noted that it is not mandatory to use a single device for both ICU and home exercising. In fact, ICU rehabilitation is to be carried out in the presence of the physiotherapist, whilst home exercising can be carried out autonomously by a patient. In this sense, different features may be required. One example of a device to be used in the ICU is [34], where a 1 DOF mechanism is used for the rehabilitation of the lower limb of an imbedded patient.

5. Requirements for Updated or New Solutions

Since the current pandemic has altered common rehabilitation practices, it is important to update or design new solutions to cope with the new needs. Since ICU devices are to be used by specialized personnel, existing solutions can be used in hospitals. However, current solutions for home training and exercising are not mature yet. Thus, research should focus on these devices since telerehabilitation and exercising are nearly required and convenient.

In this sense, a home-use device should be:

- Cost-oriented: more and more people require rehabilitation and exercising after COVID-19 recovery, so it is important to reduce both the production (and sale) and operation cost to better reach patients at an affordable budget.
- Lightweight and compact: the device should be easy to carry around the house and should be compact to improve home delivery.
- Easy to use: Even if telerehabilitation is carried out, a patient should be requested to perform some exercises on its own. In this scenario, the device should be easy to use by a patient to ensure good rehabilitation and exercising results.
- Durable: Different patients may provide different care to the equipment. To reduce broken equipment (thus increased costs), the device should be durable, even after several cycles of treatment (and different patients).
- Easy to disinfect: If the rehabilitation phase is limited, the same device could be cleaned for reuse and even be given to another patient. The number of parts and gaps should be reduced, and the materials used should be compatible with the disinfection processes.
- Safe: Apart from the rehabilitation process, the device should not harm the patient in other ways. Safety measures must be implemented in the control design and operation, and with proper control by using proper sensors.

6. An Example: CADEL Solution

All the aspects discussed above can be conveniently clarified with an example.

Such an example of a device, which is suitable for home use, is CADEL (cable driven elbow assisting device), whose design idea dates back to 2010 [35]. After some refinements, a functional design was published in 2019 [36].

With reference to the requirements in the previous section, the CADEL is lightweight thanks to its 3D printed structure and cable-based actuation. The low cost of its components ensures an easy replacement in the case of damaged parts and, being mostly made of plastic materials, the device is also easy to disinfect. The actuating cables are intrinsically safe for the user thanks to the lack of moving parts with high inertia often seen in other devices. User-oriented operation is ensured by simple control interfaces.

The original CADEL design, developed in 2017 [37–39], as shown in Figure 4a, had some issues: Firstly, it was bulky and not comfortable for the patients. Secondly, it was

not easy to wear, even for a young person with full limb functionality. Thirdly, it was not easy to use, as the cables were not always in tension, so its performance was not consistent throughout the tests.

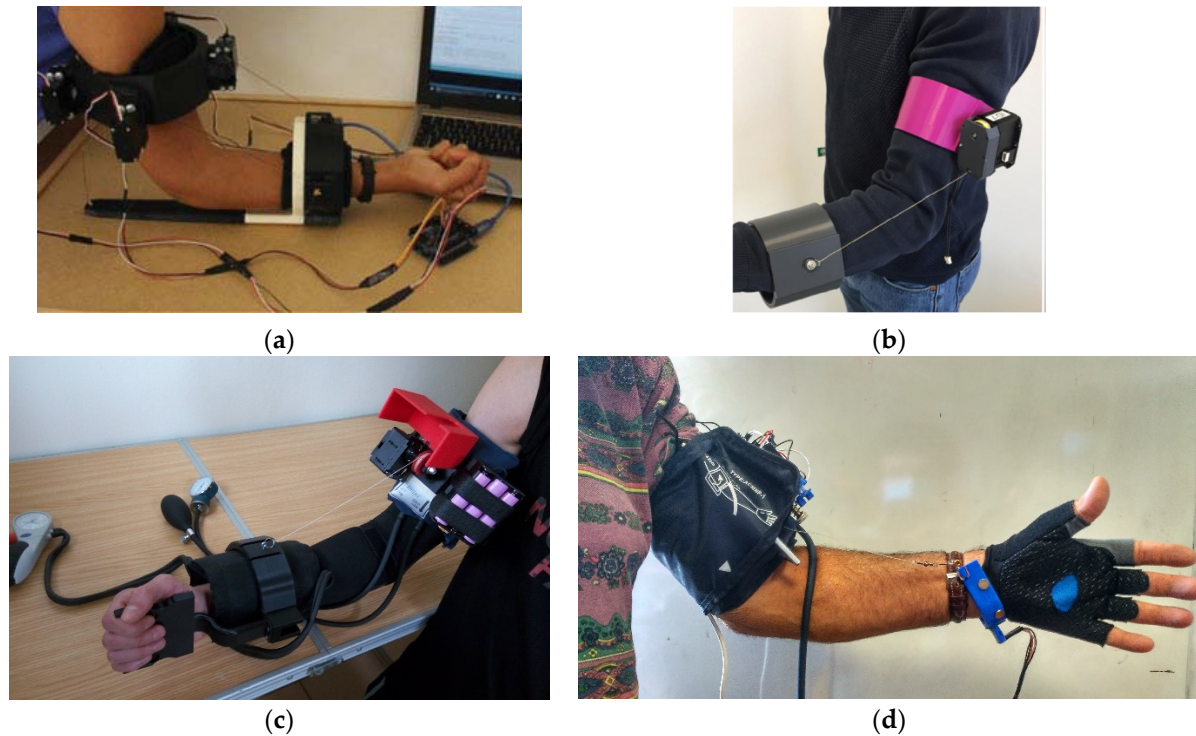


Figure 4. CADEL design for elbow motion assistance: (a) first design in 2017, [35]; (b) CADELv2 version in 2019, [41]; (c) L-CADEL version in 2020, Reprinted from Ref. [40]; (d) L-CADELv2 version in 2021, [42].

To overcome such issues, new versions were proposed from 2019 to 2021 [40–42] (summarized in Figure 4): such versions are lighter, easier to wear and to use, and can be easily controlled, so they are suitable also for home use.

As can be noted in the designs in Figure 4, CADEL is made of two rigid platforms (arm and forearm platforms) connected by cables. Such cables are moved via servomotors fixed to the arm platform. To ensure that the platforms are centered around the patient arm and forearm, between the platform and the elbow guard, two air-fillable components are placed, which can be inflated to ensure stability. The control system of the servomotors is fixed to the arm platform, and it can be controlled externally via PC or via direct devices such as buttons.

The design of L-CADEL is shown in Figure 4c,d, with upper and lower modules in a mechanical structure whose components are easily wearable on the upper part of the arm and at the wrist zone, respectively. The structure of the upper module is the fixed platform, and the lower module corresponds to the mobile platform of a cable-driven parallel manipulator, as with the original CADEL design shown in Figure 4a,b. The improvements were made to increase portability and user comfort. In fact, the upper module is made of two parts: an inflatable cuff and a lightweight plastic arc-shaped platform. Actuators and other components are installed on the latter with design features for easily customizing and adjusting to specific user conditions and requirements. The inflatable cuff is taken from a conventional manual blood pressure monitor, further supporting a very easy understanding and operation with an interface fixing the device to the arm. The cuff is attached to the arc-shaped platform with a hook-and-loop fastener and two strings (not clearly shown in Figure 4). The arc-shaped arm ring platform also functions as a frame on

which actuators tensioners, power source, Arduino Nano, and DC-DC step-up converter are fixed. The lower module is made of a glove and a lightweight plastic arc-shaped forearm ring platform.

A prototype of the last proposed L-CADEL v2 device has been built at the LARM2 laboratory in Rome, as shown in Figure 4d, with the dimensions for an average human arm but still adjustable within a significant range. The ring platforms of the two modules are manufactured with 3D printing in PLA. Parallax servos with continuous rotation and a maximum torque of 27 N cm are selected as actuators that are controlled with an Arduino Nano and are powered by three AAA batteries to provide 5.5 V. The Arduino board is provided with a buzzer indicating start, stop, and low battery charge. The operation performance is monitored with an IMU (inertial measurement unit on the lower module). The current consumption of the servomotors is monitored with two current sensors, and the muscle activity of a user is detected with EMG sensors, as an example of additional medical sensors (e.g., for temperature, blood pressure, and so on).

The practical implementation of the various prototypes described above was tested with laboratory tests in test sessions repeated at least three times with the same students involved in the project during sessions with exercises with the following general characteristics: duration of each experiment in three cycles of push-ups of the arm for a maximum of 30 s, also exploring various ranges of joint motion with data acquisition using the sensors indicated in the various prototypes, and with specific photographic recordings.

In some cases, the experimental test validation experiments were carried out by making use of artificial arms with a robotic structure with joint motion simulation in order to also investigate the possible interaction with further motor assistance systems, as in the specific case of the prototype developed at the University of Padova.

Summarizing the evolution of the CADEL design, as shown Figure 4, main requirements have been considered in the design and operation for portability with a final solution of less than 1 kg weight, low-cost design of a lab prototype of less than 50 euro, user-oriented operation with pre-programmed control planning for regulated operation as per user needs, and easy sterilization components so that it can be adjusted both for hospital and home usage. The patient at home has to follow these steps to perform rehabilitation exercises:

- Wear the equipment.
- Adjust the ring platforms.
- Connect the cables from the arm platform to the forearm platform.
- Start the exercise.

Although CADEL specifically relates to the elbow joint, in its general form it can be used for other joints. In fact, authors have proposed a similar design for the rehabilitation and exercise of the ankle joint [43]. Moreover, the same concept may be used with existing devices (such as NeReBot) to perform imbedded rehabilitation (Figure 3).

The novelty of the illustrative example referring to CADEL solutions can be highlighted by patent productions [1–3] for such a device in elbow motion assistance with the features of portability, easy wearing, and user-oriented operation that can be properly adjusted to COVID-19 user-patients either as a single assisting device or in combination with other devices, as indicated in the example shown in Figure 3, for assessing the specific needs of the COVID-19 patients in different health conditions.

7. Conclusions

The fight against the COVID pandemic is in part carried out with technical devices supporting health conditions and recovery in terms of limb motion. Those devices, as well as improvements or adaptations of existing designs, are required with additional characteristics suitable for the specific COVID-safe use, such as easy sanitation, portability, easy user-oriented operation, and easy user-customized design and operation. Special attention must be paid to the user-patient condition as imbedded in hospitalized care assistance or home recovery, which may require direct assistance or telemonitoring by medical operators.

The reported specific case of L-CADEL for elbow motion assistance from the authors' direct experience outlines an example of a solution for the design and operation of those devices that can support the fight against COVID disease in terms of limb motion rehabilitation and exercise, and it is also useful in general physiology treatments of user-patients.

Future work is planned in collaboration with teams of medical and physiotherapist operators for the validation and medical implementation of those limb motion assisting devices and particularly CADEL solutions with clinical evidence and results.

8. Patents

Marco Ceccarelli: Ferrara Lucia, Victor Petuya, Device for elbow rehabilitation, n.102017000083887, 24/7/2017, Italy. Patent no. IT. 102017000083887–29/10/2019. Marco Ceccarelli, Bottin Matteo, Giulio Rosati Portable cable-driven exoskeleton for elbow motion assistance, n. 10202000004885, 9/3/2020, Italy (patent pending). Marco Ceccarelli, Marco Ceccarelli, Matteo Russo, Monica Urizar Arana, Mykhailo Riabtsev, Axel Fort, Mohamed Amine Laribi, Portable device for motion assistance of the elbow, n. 102021000013229, Italy, 20/5/2021 (patent pending).

Author Contributions: Conceptualization, M.C., G.R., M.A.L. and V.P.; methodology, M.C., G.R., M.A.L. and V.P.; software, M.B. and M.R.; validation, M.B. and M.R.; formal analysis, M.B. and M.R.; investigation, M.C., M.B. and M.R.; resources, M.C., G.R., M.A.L. and V.P.; data curation, M.B. and M.R.; writing—original draft preparation, M.C. and M.B.; writing—review and editing, M.C. and M.B.; visualization, M.B.; supervision, M.C.; project administration, M.C. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

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