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A Device for Local or Remote Monitoring of Hand Rehabilitation Sessions for Rheumatic Patients

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ABSTRACT Current clinical practice suggests that recovering the hand functionality lost or reduced by injuries, interventions and chronic diseases requires, beyond pharmacological treatments, a kinesiotherapic intervention. This form of rehabilitation consists of physical exercises adapted to the specific pathology. Its effectiveness is strongly dependent on the patient's adhesion to such a program. In this paper we present a novel device with remote monitoring capabilities expressly conceived for the needs of rheumatic patients. It comprises several sensorized tools and can be used either in an outpatient clinic for hand functional evaluation, connected to a PC, or afforded to the patient for home kinesiotherapic sessions. In the latter case, the device guides the patient in the rehabilitation session, transmitting the relevant statistics about his performance to a TCP/IP server exploiting a GSM/GPRS connection for deferred analysis. An approved clinical trial has been set up in Italy, involving 10 patients with Rheumatoid Arthritis and 10 with Systemic Sclerosis, enrolled for 12 weeks in a home rehabilitation program with the proposed device. Their evaluation has been performed with traditional methods but also with the proposed device. Subjective (hand algofunctional Dreiser's index) and objective (ROM, strength, dexterity) parameters showed a sustained improvement throughout the follow-up. The obtained results proved that the device is an effective and safe tool for assessing hand disability and monitoring kinesiotherapy exercise, portending the potential exploitability of such a methodology in clinical practice.

INDEX TERMS Telerehabilitation, rheumatic diseases, adapted physical exercise, rehabilitation, telemedicine.

I. INTRODUCTION

Hand disability limits a patient's activities of daily life, leading to reductions in self-sufficiency and deterioration of quality of life. This condition can be caused by injuries, surgery and diseases. Its onset can be sudden or progressive, entailing different therapeutic approaches. Recovering hand function requires pharmacological treatment together with a rehabilitation protocol including therapeutic exercises (kinesiotherapy) adapted to the patient's specific needs [1]. According to the American Kinesiotherapy Association, kinesiotherapy is the application of scientifically based principles to design specific exercises aimed to enhance the strength, endurance, and mobility of individuals with functional limitations which require extended physical conditioning. A kinesiotherapic exercise program, prescribed by health professionals, is often a necessary step for individuals who have been inactive, suffer a reduction in joint motion or muscle strength, are experiencing joint pain or are recovering from active disease [2], [3]. Active kinesiotherapy, consisting of both flexibility and strengthening physical exercises adapted to the special needs of patients with Rheumatoid Arthritis (RA) and Systemic Sclerosis (SSc), has been demonstrated to be useful in

recovering, maintaining and improving hand function in these rheumatic diseases [4], [5]. RA is a systemic chronic inflammatory disease, primarily affecting synovial joints, mostly at the hands, characterized by the development of fibrosis in joints and tendons and by the progressive erosion of cartilage and bone, which can lead to substantial loss of functionality and, in late stage, deformities. RA has a worldwide distribution with an estimated prevalence of about 1% and mainly affects 30-50-year-old females [6]. SSc is an autoimmune disease that targets the microvasculature and leads to fibrosis in the skin, the muscoloskeletal system and internal organs. Thickening of the skin of the hand and tendon retraction can result in contractures of the fingers, determining hand impairment [7].

In such diseases, kinesiotherapy aims to: (i) strengthen the muscles and provide greater joint support reducing load and stress through the affected joints, (ii) maintain or improve the flexibility in affected joints and surrounding tissues, (iii) help reduce bone loss related to inactivity, inflammation and the use of specific medications (e.g. corticosteroids) [8], [9].

Active kinesiotherapy would require constant monitoring by health professionals but often it is impossible to closely assist every patient, because of the reduced availability of specialized facilities and qualified staff. Therefore it is common practice that active kinesiotherapy is performed at home using common objects (e.g. elastic bands) and self-managed by patients after an appropriate training. Such an unsupervised scenario leads to the impossibility of assessing whether the protocol is correctly followed or not, which has implications on its effectiveness [10].

In this paper a solution mixing on a single device both a local and a remote monitoring system for hand kinesiotherapy is presented and evaluated. The device has been designed thanks to a tight cooperation between a bioengineering unit and specialists in rheumatology, starting from the current state of the art and introducing novel experimental protocols. The proposed low-cost device allows a simple and objective monitoring of the patients' rehabilitation sessions through a set of custom sensorized tools. It can guide the patient by means of a simple user interface for home sessions, whereas for outpatient clinic evaluations the same device operates as a PC peripheral. The remote operating mode is supported by an embedded GSM/GPRS module able to transmit the main statistics about the rehabilitation session to a TCP/IP server for deferred analysis. From there, data can be retrieved as needed for local analysis: this functionality is supported by a custom software framework. A clinical trial involving 20 patients with RA and SSc has been used as testbench for the proposed approach. During a period of 12 weeks the patients have been monitored exploiting the telemonitoring option in order to provide a support of information for the patient-doctor interaction. The patients' hand functional evaluation has been performed with traditional methods and with the proposed device, revealing the effectiveness of the approach and highlighting some aspects that can be further studied in order to improve the reliability and reproducibility of the system.

The remainder of this paper is organized as follows. In Section II a brief analysis of the state of the art in the field is provided. Section III presents the design and implementation of the proposed device, whose external telemonitoring infrastructure is briefly described in Section IV. The results obtained in the first clinical trial and the conclusions are presented in Sections V and VI respectively.

II. STATE OF THE ART

The kinesiotherapic protocol for RA and SSc patients is an open research issue [1], [9]. The most frequent approach is the definition of a series of exercises the patient can perform at home using objects of daily life [11] such as flexo-extending the fingers with a counter resistance applied (using a rubber band), pressing each fingertip against the thumb, repeatedly screwing in and unscrewing a screw with a screwdriver, rolling a newspaper page into a ball, and others. By their very nature, these exercises cannot be easily standardized in order to ensure the correct execution at home. Furthermore, relying on unsensorized objects, they cannot be quantitatively monitored in local or remote scenarios for the evaluation of the functional deficit. This evaluation is rather performed in a clinical setting using biomechanical measurements such as the Range Of Movement (ROM), hand extension and strength. Also questionnaires gathering the patient's perception of his or her disability, e.g. the Dreiser test [12] are used for this purpose. Some systems, such as the Jamar dynamometer (isometric) and the Vigorimeter (dynamic), allow the clinical evaluation of the grip strength [13], whereas some others also allow the evaluation of the single finger pinch force (e.g. Jamar Pinch Gauge). Some devices such as the H500 H and Kit by Biometrics Ltd. allow monitoring both of them in multiple repetitions. These devices are only suitable for one-shot functional assessment, as they are not designed as tools for rehabilitation purposes. The commercial Pablo system by Tyromotion GmbH, designed for neurological rehabilitation, allows performance of several rehabilitation exercises but only grip strength, single finger pinch force and indirect ROM of the wrist can be measured for functional assessment of the hand.

Nowadays the majority of studies on hand rehabilitation are focused on post-stroke patients, who usually need to relearn the movements. For this purpose, many prototypical robotic systems have been presented, such as the HandSOME device [14] for the pinch-grasp movement, the actuated thumb exoskeleton (ATX) [15] or the HANDEXOS [16] wearable multiphalanges device. These systems are quite expensive and not usable for telerehabilitation purposes yet. Also, they are unsuited for rheumatic patients, who frequently present hand deformity caused by the illness's progress. There are also some commercial robotic devices such as the Amadeo System (Tyromotion GmbH) and the Hand Mentor (Kinetic Muscles Inc.) but their applications are constrained to specific movements, often requiring the support of specialized

IEEE Journal of Translational Engineering in Health and Medicine

nurses, representing a justified approach only for paralyzed patients.

Some systems in literature exploit sensorized tools to allow the monitoring of active rehabilitation exercises. These systems are usually low-cost and easy to transport, so they are suitable for a telemedicine approach. For example, both the devices presented in [17] and [18] exploit a tracking system for the upper limb monitoring and a graphical user interface on a PC to guide the post-stroke patient in the exercise execution and to send the monitored data to the physician. The system presented in [19] enables the evaluation of the follow-up of hand-transplanted patients. It includes a commercial sensorized hand glove (HumanGlove by Humanware s.r.l.) to perform kinematic assessment of the hand and the fingers, and two devices for the mechanical evaluation of the force of the hand and fingers, and it is managed by an acquisition software on a PC with data storing onto a web server. These exercises are not specifically designed for the described dysfunction and the use of these sensorized gloves is not suitable for patients with hand deformity. Another example of a telerehabilitation system has been presented in the European project HELLODOC [20] for the recovery of the upper limb in neurological patients. It includes a portable unit based on a desk installed at the patient's home providing a computer and a set of sensorized daily life objects for the monitoring of some parameters during their use. An in-hospital server allows the clinicians to remotely monitor these parameters. Such a device is closer to the one presented in this paper.

In the last decade virtual reality has been introduced in rehabilitation devices, improving the quality of the patient interaction with the rehabilitation system [21]. Such systems require the use of a PC or a game console [22], which manages the rehabilitation session and the communication from the patient's home to the physician's PC through a wired connection, thus requiring a physical installation in the patient's home. The majority of them require a great effort for both the physician in interpreting the acquired data [23] and the patient in learning how to interact with the system [10].

III. DESIGN OF THE KINESIOTHERAPY DEVICE

The first step of this research has been the development of a set of adapted physical exercises able to improve both the strength and the agility of patients with RA and SSc. Taking into account the common peculiarities of the two diseases, RA and SSc, the strength exercises were conceived and evaluated with the goal of avoiding joint stress and overload. To this aim, all of them require isometric muscle contraction, and should be tailored by the patients at a pain-free intensity. During isometric contraction the muscular contractile component shortens and stretches the elastic component, without changing the joint angles involved in muscle work, thus preventing relapse of inflammation in affected joints. Conversely, the agility and stretching exercises, which are obviously dynamic, should present the minimum counter-resistance in order to emulate a tool-free exercise. Overall, the wrist should not be used as a lever but only as a support for the hand, leaving to the fingers the exercise effort, in every exercise. Seven different exercises have been conceived, all of them requiring multiple series, each one composed of multiple repetitions of the same gesture. Among them we have isometric exercises:

E1. hand pinch
E2. hand grip
E3. finger pinch (opposition to the thumb)
E4. rotation (screwing with the fingers)

and dynamic ones:

E5. hand extension
E6. rotation (fast manipulation)
E7. finger tapping (piano-like)

Despite the differences between the two rheumatic diseases, the proposed set of exercises is able to cope with the needs of both the populations of RA and SSc patients, producing significant improvements in their strength, agility and dexterity, as will be clear in Section V. At the same time, they probably could be successfully applied to other pathological conditions that require the same characteristics of the rehabilitation exercises, which may, open the proposed device to a wider application scenario.

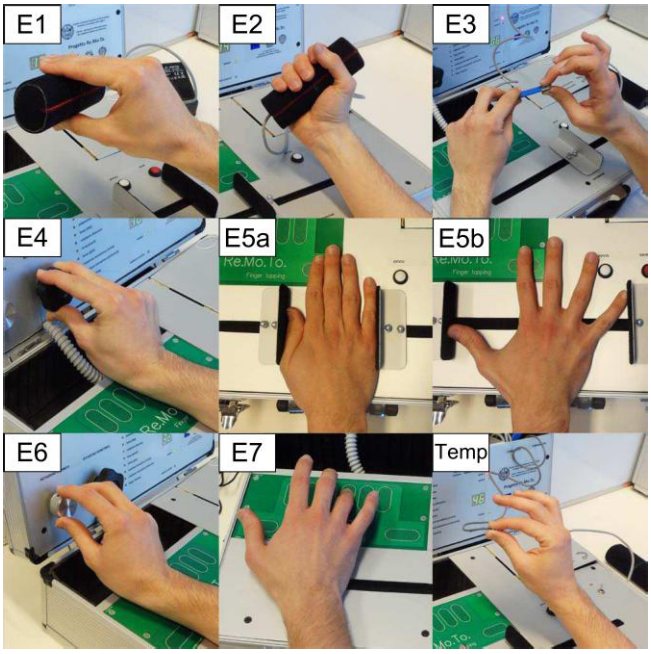

FIGURE 1. The different exercises and the related tools (plus the temperature sensor) supported by the proposed device.

A. TOOLS AND SIGNAL PROCESSING

The exercises have been engineered with the sensorized tools depicted in Fig. 1 and embedded in a portable device:

1) a tool for hand grasping exercises in pinch and grip (E1 and E2), which exploits a low-cost Flexiforce A201 force sensor by Tekscan (max force in linearity response: 440N), pressed between the two halves of a handle covered with neoprene;

2) a tool made of an aluminum plate which sustains a Flexiforce A201 force sensor (110N). Its sensible area can be pressed against the plate through a silicon pad, with a finger acting in opposition to the thumb (E3);
3) a tool with an exposed 5-lobe nylon handle which cannot spin but it is internally fixed to a bar which in turn presses one of two Flexiforce A201 force sensors (110N) as a torque is applied clockwise or counterclockwise respectively, using the fingers only (E4);
4) a tool based on a moving metal structure, made of two rollers (CES30-88-ZZ by Rollon) on a rail for linear movement (TES30-1040 by Rollon), connected by an analog draw wire position sensor (LX-PA-15 by TME) which provides information on the relative distance between the rollers. The rollers are actuated by the patient, who inserts the hand between the two metallic profiles attached to them, by opening and closing the hand (E5). A small counter-resistance (about 4N) needed for the rope winding is opposed to the extension movement;
5) a tool consisting of a multi-turn precision potentiometer (Vishay 534, 10 rounds) with an aluminum knob attached to its shaft. The resistant torque of the potentiometer is negligible (0.006Nm), providing a support for a low-resistance dynamic rotation exercise. The patient is asked to spin the knob using the fingers only, both clockwise and counterclockwise (E6);
6) a capacitive touch board for a finger tapping test (piano-like) [24]. The tool comprises 8 sensible areas which are scanned continuously by an MSP430F2013 microcontroller unit (MCU) in order to detect which areas have been touched. The patient is asked to touch 5 of the 8 available sensible areas with the fingertips in order from the little finger to the thumb as fast (and precisely) as possible (E7).

Additionally, a skin temperature probe (NTC thermistor YSI 400 compatible) has been integrated to measure the temperature of the hand (between thumb and index) at the beginning and at the end of the session. Taking into account the two rheumatic diseases, this sensor has been included to evaluate the effect of the exercise session in SSc patients, where one of the objectives is to increase the blood inflow to the affected tissues. RA patients have been asked to measure the acral temperature only for comparative purposes.

The choice of the sensors and the consequent design of the tools have been driven by simplicity for the patients and a good trade-off cost/performance. Each tool, except the one for E7 which provides a digital signal and is accurately described in [25], is interfaced to the MCU in charge of controlling the device functionality through a signal conditioning stage, before digitalization. Signal conditioning consists of low-pass active filters based on the TLV2375 operational amplifier. Since all the signals coming from the sensors are unipolar, a single supply configuration without any biasing circuitry can be employed, thus limiting the stage complexity and the number of resistive elements, also reducing the mains interference. A single pole RC cell sets the cut-off frequency at 48Hz, acting as anti-alias filter for the sampling, performed at 150Hz by the MCU through the internal A/D converter in order to guarantee an adequate time resolution for the signal processing algorithms.

All the used sensors are resistive; this leads to fairly simple conditioning circuits. The temperature sensor is inserted in the filter feedback line of an operational amplifier, in a circuit calibrated to measure a skin temperature in a range from 20 to 40 °C. All the Flexiforce sensors are inserted between ground and the inverting input of an operational amplifier, making the stage a variable gain amplifier. Providing to the non-inverting input a fixed voltage, obtained by means of a 0.5V reference and an RC cell, the output voltage varies linearly with the force applied to the sensor. Both the Vishay 534 potentiometer and the TME LX-PA-15 draw wire sensor are inserted in a voltage divider, with the wiper connected to the non-inverting input of an operational amplifier through an RC cell, so that the output value is proportional to the voltage at the wiper.

The signals coming from the tools equipped with analog sensors are processed exploiting three different algorithms, whose use depends on the shape of the signal to be processed. Such a processing is useful for the online extraction of the statistical parameters related to the execution quality, presented for the different exercises in Table I. The extraction of these parameters from the raw signals is briefly described hereafter.

TABLE 1. Relevant parameters for the statistical summary associated to the different exercises.

Exercises	Extracted Parameters and Related Statistics
E1, E2, E3 [E4, E5]	• Force [torque, extension]: max, min, avg, std • Repetitions duration (only the active part): avg and std • Number of repetitions
E6	• Rotation angle and rotation speed: avg, std • Exercise duration • Number of repetitions
E7	• Duration of correct/wrong sequences: avg, std • Number of touches per second • Number of correct/wrong sequences

avg: average; std: standard deviation.

All the isometric exercises (E1-4) and the extension one (E5) yield a peak-shaped waveform, where each peak represents the patient's action on the device. A threshold-based algorithm detects the peaks, extracting their magnitude, duration and distance. The minimum detection threshold for E1-4 has been defined by the specialists for the different exercises whereas for E5 it has been imposed by the designers. For E5, the system performs a zero-calibration with the closed hand of the patient so that the effective extension is measured.

E6 yields a terraced waveform, where each plateau represents the release phase (when the patient releases the knob for the next repetition) and the edges represent the phase when the patient spins the knob with his fingers (as depicted in Fig. 1). The algorithm detects the edges and extracts their amplitude and duration, respectively leading to the rotation angle and speed, and the plateau duration. The signal segmentation

involves the identification of parts where the amplitude is substantially constant, after a moving average smoothing.

The signal processing for the tapping exercise E7 is based on the analysis of the digital words coming from the sensor by a masking procedure in order to recognize a valid sequence, allowing the patient to perform the exercise either leaving in place the finger after a touch (but detaching them after the sequence has been closed by the thumb) or detaching them (one or more at a time) after a touch. The details have been presented in [25].

For the temperature, the algorithm detects when the signal becomes stable (i.e. its variation is under an empirical threshold) and then extracts a stable voltage value proportional to the resistance by averaging a few samples in order to smooth the noise.

The proposed device embeds all the aforementioned tools, providing all the electronics for the signal acquisition, processing and transmission.

FIGURE 2. The appearance of the proposed telerehabilitation device.

B. DEVICE STRUCTURE AND CONTROL

In order to guarantee both robustness and portability, the device has been embedded into a metal briefcase. Its final appearance is shown in Fig. 2. An ultra low-power MCU, the MSP430FG4618 by Texas Instruments, is used for managing the whole system. The device handles only the integer values coming from the A/D converter, limiting the number of computations induced by the fixed-point numerical representation on the MCU. The conversion into the corresponding physical quantities exploiting the calibration values embedded into the device software is performed either on the device (only on the statistical summary, at the end of the whole session, just before data transmission) or on the PC when a therapist is locally controlling the device in real-time.

The underlying design idea is that the same computerized device should be able both to guide the patient in the execution of the exercises when he performs the kinesiotherapic session at home *(deferred telemonitoring mode)* and to execute the commands issued by a PC under the local supervision

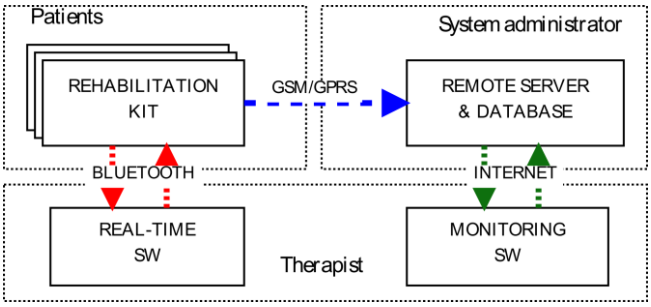

FIGURE 3. Main components of the telemonitoring system for hand kinesiotherapy.

of a therapist *(real-time control mode)*. The latter operating mode is useful either for rehabilitation sessions performed under the direct supervision of a therapist or for the functional evaluation of the hand in the context of a therapeutic exercise. Such a research is the natural consequence of a previous work in the field [25], which was limited in the number of exercises and did not include any telemonitoring support. Fig. 3 shows how the different elements of the proposed system mutually interact, highlighting the area of interest of each user in the different scenarios.

The communication features are implemented by means of an internal GSM/GPRS module (SIM900 by SimCom embedded on the 8100-TDGGMSM_900 board) interfaced to the MCU USART port and an external Bluetooth one (WT11-A-AI by Bluegiga) interfaced to the USCIA port. The choice of an external Bluetooth module is dictated by the need of providing such a functionality only to the therapist. The connection mean is a 25 poles D-Sub female connector hosted on the front panel of the device (also enabling the MCUs programming). A 2m cable allows putting the GSM/GPRS antenna far from the metal case of the device and from the patient.

Notably, the system is battery powered so also a power connector (for charging only), a charge LED and low-battery LED are included. The device has been designed including several security mechanisms against macro-shocks (e.g. no operation when charging) and mechanical injuries (e.g. soft materials, rounded edges). Even though it is always difficult to evaluate the final cost of a device, when it is in its prototypical form, from a simple estimation of the manufacturing costs including the materials, a value of about 700 Euros per device can be computed. This estimate does not include the researcher's and designer's wages.

1) DEFERRED TELEMONITORING MODE

When the device operates in deferred telemonitoring mode (no Bluetooth module connected at boot), it launches a programmed sequence of rehabilitation exercises and collects, during the execution, the statistics representative of the patient's performance, storing them until the end of the session. The MCU firmware controls the patient interface on the device in order to assist him during the exercise execution,

enabling a simple training experience. The patient interface is minimal in order to be accessible by elderly people. It consists of an on/off switch and two push-buttons (for starting a series and for skipping a single repetition) for the input, a buzzer and several LEDs for the output (one LED for every exercise, in order to pinpoint the exercise to be performed, 2 LEDs to identify which hand must be used, 2 LEDs for the first and second series, one LED blinking at 1Hz for a time reference in the sustained exercises) plus a multi-purpose 7-segment display. The latter is used alternately to show the number of correct repetitions performed within a series, the percentage of effort related to the full sensor range, the elapsed time for the temperature, and other exercise-specific feedbacks.

In this operating mode, the raw signals are used to extract the performance parameters in real-time, but then they are discarded. At the end of the rehabilitation session, a local vector is filled with the related statistical summary and it is sent to the remote server via a TCP/IP connection established by the embedded GSM/GPRS module. The data is sent as a binary stream without encryption since no sensible data are sent and the patient is identified only by the unique International Mobile Subscriber Identity (IMSI) code of the SIM card hosted by the GSM/GPRS module. If the communication aborts, after a limited number of trials the data is stored into the MCU flash memory, informing the user through the 7-segment display, allowing him to safely turn off the device. At the next switch on, if data are present in the flash memory a further forwarding attempt is performed, overcoming a temporary network or server malfunction. The role of the different actors involved in this scenario is depicted in Fig. 4. Details on the client application are given in Section IV.

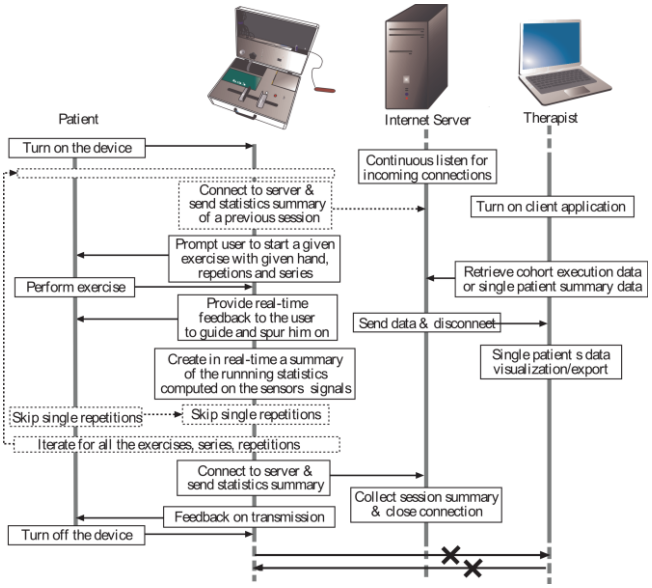

FIGURE 4. Deferred telemonitoring operating mode.

2) REAL-TIME CONTROL MODE

When the system is in real-time control mode (which happens when, at switch on, the MCU detects the Bluetooth module), after a handshake including the calibration constants transmission to the PC, the device puts itself in stand-by. On the PC, a standalone C++ software application based on the Qt framework v4.7 [26] and exploiting the third party library QextSerialPort for handling the communication with the PC's Bluetooth adaptor, gives to the therapist the possibility of controlling the device. An exemplary screenshot of the therapist interface is shown in Fig. 5.

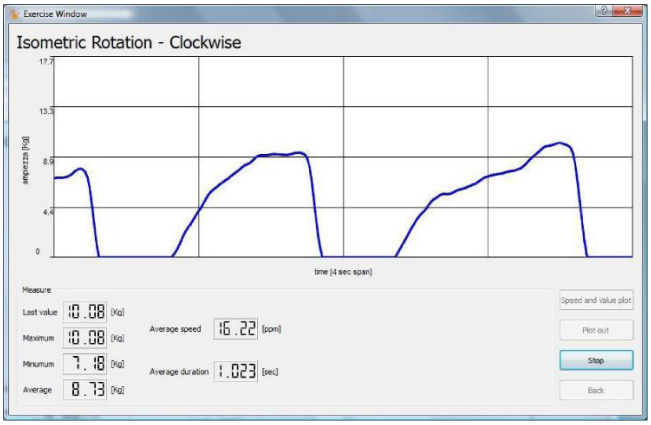

FIGURE 5. Therapist's real-time control interface.

As soon as an exercise is chosen, all the on-board resources are initialized and, after the exercise is started by the patient, both the raw signal and a vector containing the running statistics on the extracted parameters (once per second) are sent to the PC in real-time. The real signal, scaled by the host taking into account the calibration constants, is shown on the therapist's real-time control application along with the running statistics, until the exercise is either aborted or completed. The patient interface on the device operates in the same way as in the deferred telemonitoring mode. During the experimental trial, the real-time control mode has been used for training the patients and for periodic outpatient clinic evaluations. The role of the different actors involved in this mode is depicted in Fig. 6.

IV. THE EXTERNAL TELEMONITORING INFRASTRUCTURE

In order to enable the telemonitoring feature, the system has been completed with a server application and the therapist's client application for the patient's performance evaluation. Both software components have been developed in C++ exploiting the support of the Qt framework. In this implementation, the server exploits a SQLite database.

The data sent by the devices are interpreted on a positional basis in order to store them in the database. To access the data, the client can build requests to create queries (actually formed by the server after request decoding). The retrieved data is organized in frames, containing the parameters relative to a rehabilitation session of a single patient.

To protect the database integrity, it is not possible to delete any data using the therapist's client application. Data downloaded from the server are stored in a portable file

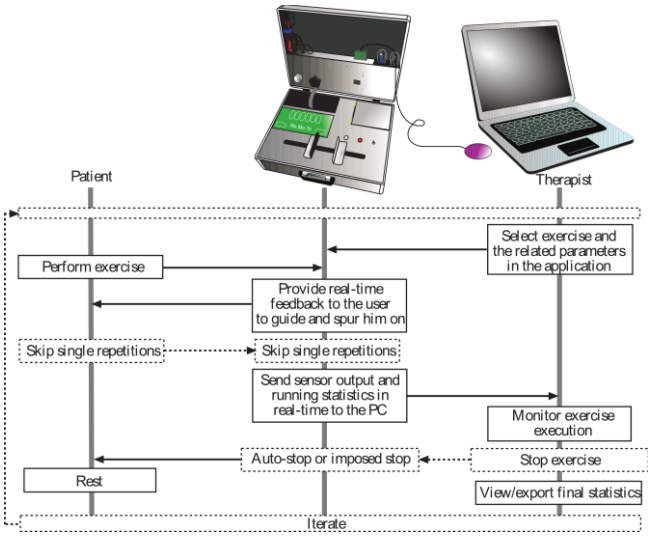

FIGURE 6. **Real-time control of the device.**

format (.csv) for further analysis in external programs. The monitoring application offers a bird's eye view of the patient's compliance by a table clearly showing when the patients have performed the rehabilitation session and when not. In a second window, the performances relative to each exercise for a given patient can be graphically visualized. An exemplary view of the two windows is shown in Fig. 7. These quantities can be used to gather clues on the quality of the rehabilitation session. For instance, in strength exercises the force values are connected to the execution speed, since the faster the action the lower the force. A poor patient performance should be evaluated in the light of such considerations.

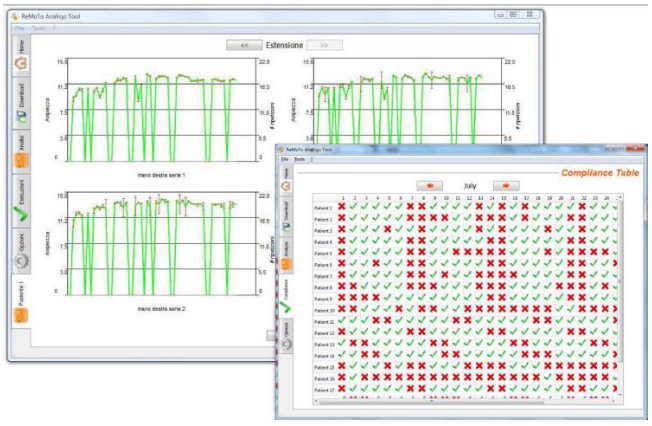

FIGURE 7. **The monitoring software: a view of the main client monitoring software windows.**

V. THE CLINICAL TRIAL RESULTS

A clinical trial with a non-CE marked medical device, reviewed and approved by the Italian Public Health Department, has involved 10 patients affected by RA and 10 by SSc. Since established guidelines for rehabilitative exercises actively performed by patients are still lacking, the trial was not designed to compare the results of the patients using the presented device and methods against those performing a "standard" rehabilitation. The primary outcome of this pilot study is the evaluation of the degree of functional improvement with respect to the baseline of the patients. The two groups were selected in order to have similar characteristics. According to the epidemiology of the single diseases, ages were between 39 and 74 (median 55.5) for RA and between 44 and 73 (median 56.5) for SSc. All the patients were trained in the autonomous use of the proposed device by the specialists and then the devices were entrusted to them for 12 weeks in order to perform the kinesiotherapy at home. The kinesiotherapic protocol was approved by the Ethical Committee of the AOU of Cagliari (Italy) where the trial took place. It defined the order and the number of series/repetitions for each exercise and the number of weekly rehabilitation sessions (5 per week). As explained above, the protocol was the same for both SSc and RA patients. This allows highlighting the effectiveness of the proposed approach. During the trial, the specialists avoided frequent interventions to stimulate a satisfactory execution of the exercises. The trial was performed according to the principles of Good Clinical Practice and the Declaration of Helsinki.

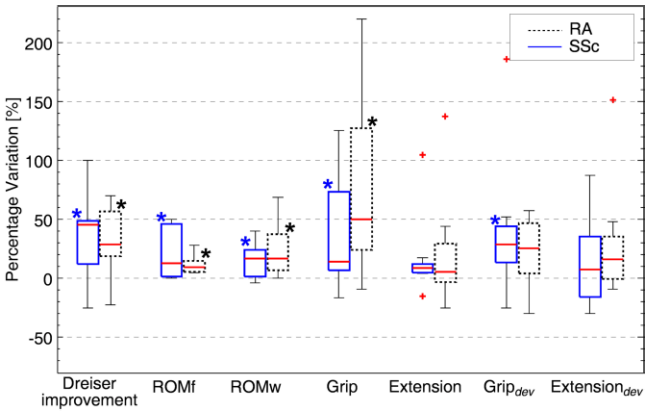

FIGURE 8. **Box plot of the percentage variation of some functional hand parameters at the end of the trial (T2) with respect to the beginning of it (T0). Median is highlighted, crosses represent statistical outliers. ROMf: ROM finger flexo-extension; ROMw: ROM wrist flexo-extension. Subscript dev indicates measurements performed with the device. Statistically significant improvements of the parameters have been marked with asterisks.**

In clinical practice, hand disability is assessed through the hand algofunctional Dreiser index, the grip strength is measured by asking the patient to grasp a sphygmomanometer cuff inflated at the standard pressure of 20 mmHg, the joint ROM (related to the wrist and fingers flexion-extension) using a goniometer and the hand extension ability on the plane. Patients were evaluated in the outpatient clinic, by the same health professional, at the beginning (T0) and at the end (T2) of the trial using both the described standard indexes and an unique device identical to the one used at home for the everyday training for a more effective comparison. Fig. 8 and Fig. 9 show the percentage variation (with respect to T0) of these indexes at T2, using the dominant hand (the right for all the patients). The box plot highlights the median value and

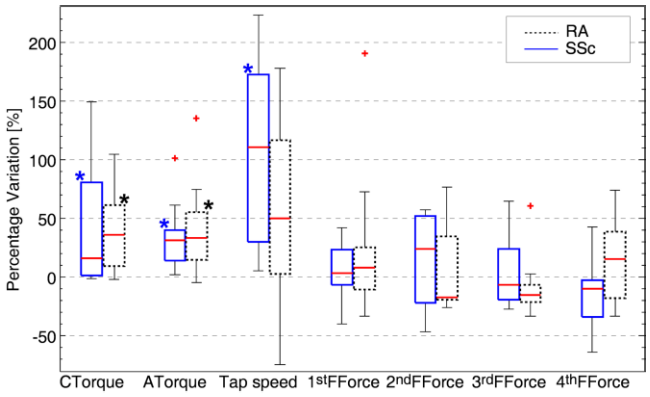

FIGURE 9. Box plot of the percentage variation of some functional hand parameters at the end of the trial (T2) with respect to the beginning of it (T0). Median is highlighted, crosses represent statistical outliers. All the measurements were performed with the device. CTorque: clockwise rotation torque; ATorque: anticlockwise rotation torque; 1^{st}-4^{th}FForce: fingers force in opposition to the thumb. Statistically significant improvements of the parameters have been marked with asterisks.

the 25th and 75th percentiles, whereas the whiskers span the range of the outermost samples not taken as outliers (that in turn are identified as crosses in the graph). In order to highlight those parameters showing a significant within-subjects improvement throughout follow-up, the pre-test vs. post-test results were compared using the paired sample Wilcoxon test. Statistically significant values were considered for a p value less than 0.05 and they have been marked in figures with an asterisk.

The increase in the four indexes ordinarily used in clinical practice (ROM fingers, ROM wrist, grip and extension), as depicted in Fig. 8, highlights the actual improvement of the patients' physical performance at the end of the clinical trial. The same increasing trend is shown by the other parameters in the two figures, measured with the proposed device, proving the significance of the proposed method according to the standard evaluation methods. The discrepancies between the grip and extension results, with or without the device, can be ascribed to the different modalities that characterized the test execution. In fact, the device measures an isometric grip force whereas a non-isometric grip is performed during the traditional assessment. Similarly, hand extension measurement with the device imposes a counter-resistance, not present in the traditional assessment.

In order to use a typical clinical index for the evaluation of the patient's health perception, the Dreiser index was also analyzed in the same time frame. The percentage reduction of this index for both RA and SSc patients is depicted in Fig. 8. It should be noted that the reduction of this index in T2, with respect to T0, corresponds to a better perceived hand functionality, so the result in Fig. 8 is expressed as a positive percentage variation even though actually such an index decreased over time.

The proposed device allows the evaluation of other strength/agility parameters not used in the clinical practice, whose percentage variations are shown in Fig. 9. The first three indexes highlight an increasing trend in clockwise/counterclockwise rotation torque (E4) and in the finger tapping (E7) speed. The improvement of the latter index is due both to the improvement of patients' agility and to their ability in learning how to execute the exercise, proved by the correlated increase of the right number of touches. The last four indexes, representing the trend of the finger pinch exercise (E3), show worse results. These are supported by the telemonitoring data which show that the time spent in the exercise and the performance tend to decrease after the very first days, becoming stable, despite the overall improvement in the hand functionality. Further investigations revealed that the exercise was perceived as being really difficult for almost every patient. Since the proposed threshold technique gives the patient a feedback (a chiming buzzer) as soon as the minimum required effort is reached, the patients were prone to execute this exercise with the smallest effort, avoiding applying the maximum force. In a future trial such a feedback will be modified in order to avoid this issue, providing a goal for the patient.

We also observed that the values of dynamic rotation angles (E6), not presented here, are not realistic, since the patients tend to cheat the exercise when rotating the knob, spinning it in order to exploit its inertia thus achieving very large angles, above physiological limits. This is completely perceivable from the remote monitoring and has been confirmed by the periodic evaluations of the patients. Such a result highlights the limits of an autonomous home rehabilitation system which can be cheated by non-conscientious patients. The introduction of a counter resistance in the rotation knob would avoid the free rotation, thus reducing this problem. It will be interesting to see whether such a hardware control is able or not to provide the same results that a doctor-patient interaction would in the light of the telemonitoring data.

Although a study on acral temperature regulation would require taking into account several influencing factors, exploiting the embedded temperature sensor we observed an increasing trend of the mean temperature difference $\Delta T = T_{end} - T_{start}$, where T_{end} is the temperature after the rehabilitation session and T_{start} that before it. The results of our analysis are presented in Table II. As can be seen, the results suggest the efficacy of the kinesiotherapy approach implemented in the proposed device in increasing blood inflow to the hand, which was one of the goals of the therapeutic exercises for the SSc patients. They, starting from lower values of the temperature, achieve a larger improvement compared to the RA patients, who do not present such a microcirculation problem.

From a clinical perspective, the effectiveness of the kinesiotherapic sessions was demonstrated by the findings of a statistically significant improvement in both subjective (Dreiser's index) and objective (e.g. ROM, strength) parameters. At the end of the follow-up both RA and SSc patients showed an increased average amplitude of the movements (in E5, E6), a higher speed of execution (E5, E6, E7) and a better ability to perform fast and precise movements (E7).

IEEE Journal of Translational Engineering in Health and Medicine

TABLE 2. Acral temperature analysis.

Group	Hand	pre-exercise [°C]	post-exercise [°C]	P value
SSc	Dx	30.6 (±1.3)	32.3(±1.6)	<0.0007
	Sx	30.9 (±1.6)	33.0 (±1.3)	<0.0001
AR	Dx	32.5 (±2.3)	34.1 (±1.5)	<0.0005
	Sx	33.6 (±2.1)	34.9 (±1.3)	<0.0057

Average (± standard deviation)

Moreover, an increased endurance was developed, as demonstrated by the increased average duration of the strength exercises (E1, E2, E4) despite a stable average of the amplitude. These satisfactory results might also be ascribed to a very high compliance of the patients to the exercise protocol. The exception represented by E3 may be in part related to the medical need to keep the exercise intensity at a pain-free level. It can be noticed that the patients enrolled in the RA and in the SSc group achieved different results. Furthermore, as shown in Figs. 8 and 9, there is a difference in the between-subject results achieved by patients from the same group. This should not be surprising and must be attributed to the biological variability of the subjects and to the fact that the best results can only be achieved through a personalized rehabilitation program. However, for the purpose of this pilot uncontrolled clinical trial, aimed at evaluating the feasibility and effectiveness of the proposed approach, we chose to define the working parameters at the beginning and not change them over the duration of the trial in order to effect a more rigorous evaluation of the method. As a consequence, not enabling any protocol personalization, we could not ensure an equal level of improvement. Starting from the achieved results, further studies, based on adjustable working parameters, will address the effectiveness of telemonitored personalized rehabilitation programs.

VI. CONCLUSION

In this paper we presented the conception and evaluation of a portable device for both local hand evaluation and remote monitoring of hand kinesiotherapic sessions. The device, expressly designed thanks to a tight cooperation between bioengineers and rheumatologists, aims at solving some problems of the current techniques in the kinesiotherapic treatment for rheumatic patients, in particular those affected by RA and SSc. A 12-week clinical trial on 10 RA and 10 SSc patients revealed promising results. The improvement of patients' conditions was found in accordance with the standard clinical evaluation and the patients expressed their satisfaction in the QUEST questionnaire [27]. 15 out of 20 patients indicated both efficacy and user-friendliness as the main positive aspects of the device, and the related QUEST scores were 4.22 (±0.81) and 4.90 (±0.32), in a scale between 1 and 5. About one half of the patients asked about the possibility of continuing with the device after the end of the clinical trial, and none of the enrolled patients reported augmented pain associated with the rehabilitation with the proposed device. From a health-care perspective, the experimental device represents an effective and safe tool for assessing hand disabilities in patients affected by rheumatic diseases with hand impairment and provides an innovative approach to monitor kinesiotherapic home exercise in those patients who do not have access, for various reasons, to specialized centers. In future studies we plan to address the issues that arose in the clinical trial, related to the autonomous use of the device, adding novel features and studying from different perspectives the approach to telerehabilitation in patients with these kinds of disabilities.

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IEEE Journal of Translational Engineering in Health and Medicine

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