IEEE Access
Multidisciplinary | Rapid Review | Open Access Journal

Received 4 August 2022, accepted 3 September 2022, date of publication 8 September 2022, date of current version 22 September 2022.

Digital Object Identifier 10.1109/ACCESS.2022.3204969

APPLIED RESEARCH

Design of a Multi-Sensors Wearable Platform for Remote Monitoring of Knee Rehabilitation

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This work was supported in part by the Research Grant from the Enterprise Ireland (EI) through the Project SKYRE under Grant CF-2015-0031-P; and in part by the Science Foundation Ireland which are Co-Funded through the European Regional Development Fund under Grant 12/RC/2289-P2-INSIGHT, Grant 13/RC/2077-CONNECT, and Grant 16/RC/3918-CONFIRM.

This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the Clinical Research Ethics Committee (CREC) of the Cork Teaching Hospitals at the University College Cork under Reference No. ECM 4 (p) 13/08/19 and ECM 3 (u) 12/11/19.

ABSTRACT Smart wearables are a promising tool for the objective and quantifiable monitoring of patients' capabilities during remote at-home assessments. A novel platform for the remote assessment of patients undergoing knee rehabilitation has been presented in this paper, SKYRE. The challenges associated with the design of the SKYRE platform are described. The platform consists of a multi-sensor wearable garment and an associated ICT architecture, with the aim of capturing real-time objective assessment of physical rehabilitation exercises and support clinicians in their decision-making process as well as provide guidance to the end-users so as to increase their awareness and compliance. The overall system architecture is defined based on users' requirements and industrial design, and both hardware and software platforms have been thoroughly discussed in detail, including electronic design, textile integration, prototyping process, and firmware development, as well as the mobile application and web portal implementation. Multiple sensing technologies are adopted, including motion capture, electromyography measurements, and muscle electro-stimulation. The developed system, SKYRE, meets the end-users' requirements, and the validation shows that the system presents results comparable to gold-standard technologies. SKYRE therefore might represent a valid alternative for patients and clinicians willing to perform a remote objective assessment of the rehabilitation process following knee surgery.

INDEX TERMS EMG, IMU, knee, mobile application, rehabilitation, remote monitoring, sensors, smart garments, telemedicine, wearable.

I. INTRODUCTION

In 2010 the prevalence of total knee replacement in the entire U.S. population was 1.52%, equivalent to 4.7 million individuals [1]. This number is assumed to increase even further in coming decades due to several factors, such as ageing and obesity, resulting in a growing population of individuals undergoing revision surgery [1]. The main causes for total knee replacement include osteoarthritis, rheumatoid arthritis, gout, and traumatic knee injuries (i.e., patella injury, anterior cruciate ligament injury) [2]. It is well-known, indeed, that patients sustaining an anterior cruciate ligament (ACL) injury are at higher risk of subsequent knee arthroplasty in comparison with the general population [3], [4]. In particular, every year, over 200,000 ACL injuries occur in the USA alone, with >50% of the cases requiring surgical reconstruction and subsequent rehabilitation [5].

Rehabilitation aims to return patients to their pre-injury level though a process that involves the monitoring of an individual's body motion when performing movements and

The associate editor coordinating the review of this manuscript and approving it for publication was Baoping Cai.

exercises defined by clinical specialists. Currently, in rehabilitation, patient assessment is mostly based on qualitative and subjective tools [6], such as rating scales and questionnaires (i.e., KOOS, IKDC, WOMAC), which may not be adequate or sensitive enough [7]. Moreover, tracking patients' progress over time can be challenging for many physiotherapists, since therapists may have to supervise multiple patients at a time and the assigned exercises are often performed in an unsupervised manner [6] in a home environment.

In order to guarantee that an effective and high-quality treatment is also extended to patients after leaving hospitals and rehabilitation centers, tele-rehabilitation can help in the collection of objective and quantifiable data on the patients' capabilities during regular at-home assessments. Tele-rehabilitation can also enhance patient compliance and motivation, and complement the expert yet subjective judgement of healthcare specialists, possibly leading to personalized therapies [8]. As indicated by Esquivel *et al.* [9], despite some disadvantages (e.g. complexity involved in the use of technology, design and possible safety issues), the key advantage of remote rehabilitation is the potential to support change in patient behaviour, empowering active participation and living independently, with less need to travel for face-to-face sessions, thus enhancing the overall quality of health care service delivery.

A growing number of studies are now considering the impact of tele-rehabilitation on improving patient satisfaction and health outcomes, while being more affordable and accessible, particularly for people living in rural areas [8]. Tele-rehabilitation systems, with their combination of wearable sensors, virtual reality (VR) and/or educational software, can also offer individualized at-home support, providing a motivating environment for achieving the rehabilitation goals, and supporting specialists in their decision-making and disease management process [8]. The role of tele-rehabilitation is growing even further nowadays as a consequence of the COVID-19 pandemic.

As recently shown in a systematic review by Latif-Zade *et al.* [10] based on findings from 139 studies, tele-rehabilitation efficacy is similar to that of office-based rehabilitation for improvement of WOMAC in patients with knee osteoarthritis. Likewise, in another review by Petersen *et al.* [11], it was indicated that there is sufficient evidence to recommend the use of telemedical methods in orthopedics.

Several tele-rehabilitation systems incorporating wearable sensors mostly rely on the adoption of motion sensors (e.g., accelerometers, gyroscopes, and magnetometers) as their primary data source [12], [13]. Indeed, as shown in a scoping review by Small *et al.* [13], 45 studies were found using motion sensors for the patients' assessment following knee arthroplasty.

However, only a few studies so far have additionally employed electromyography (EMG) [14], thus also allowing clinicians the possibility of acquiring insights on the neuromuscular system [15]. Despite the important application of surface EMG in rehabilitation (for example, to analyze muscle dysfunction, incorrect or anomalous muscle pattern activation, or muscular fatigue) [16], most of the research involving EMG in a rehabilitation context focused on scenarios such as neurorehabilitation, stroke, pain detection, etc. and generally focusing on upper limbs [16], [17]. EMG have also been adopted to trigger feedback controls to activate VR-based rehabilitation training systems [18], or robotic treatments [19], again on the upper limbs.

Finally, electrical muscle stimulation (EMS) is also an effective intervention adopted in rehabilitation for assisting motor functions [20]. For example, Monte-Silva *et al.* [21] showed in a systematic review the positive effects of EMG and EMS on stroke upper limb recovery. However, EMS has been rarely investigated along with wearable technology in a knee rehabilitation context.

Therefore, the present study presents a twofold goal:

a. The design and development of a novel wearable hardware system, wireless, unobtrusive, easy-to-use and wear on the lower-limbs for knee rehabilitation, that integrates multiple sensing technologies (motion sensors, EMG, and EMS), and
b. the design and development of an Android mobile application, as well as a cloud infrastructure, scoring mechanism, and web-based application, for the real-time assessment and monitoring of the patients' lower-limbs during at-home rehabilitation exercises.

The ultimate objective is therefore to implement an overall end-to-end solution able to provide detailed and comprehensive kinematic and physiological knee-related biomechanics information, as well as muscle activation / stimulation capabilities to clinicians and patients, something currently not available in literature or products on the market in the field, thus enhancing patients' motivation and engagement and increasing progress awareness.

This study presents the results achieved under the project (grant number: CF-2015-0031-P) funded from Enterprise Ireland under the name SKYRE (''Smart Knee System for at-Home Rehabilitation''). The manuscript is organized as follows. Related works in the field covering both literature and products on the market are illustrated in Section II. The requirements for the system and the concept developed as a result of an industrial design process are shown in Section III and IV, respectively. The system architecture is described in Section V, while Section VI and VII describe the developed hardware and the software platforms, respectively. Validation results are shown in Section VIII. Discussion and conclusions are finally covered in Sections IX and X, respectively.

II. RELATED WORKS

A. CURRENT STATE-OF-THE-ART

As shown by two reviews published in 2018 and 2019, respectively [12], [13], a number of papers have investigated the use of wearable sensors for lower-limb orthopedic rehabilitation, Indeed, most of the considered works [22], [23], [24], [25], [26], [27], [28], [29], [30], [31], [32], [33], [34]

have used wearable sensors for the functional assessment of subjects throughout their knee/hip rehabilitation process. Generally, a tri-axial accelerometer was the most used sensor in those works, often together with a gyroscope, and those signals allowed researchers to compare pre- and post-operative metrics like symmetry and variability, the dynamic range of motion, and a wide variety of spatio-temporal gait parameters (such as walking speed, cadence, stride length, stride time, stance time, vertical displacement, swing power and foot fall).

With the goal to expand upon those results, in the last couple of years, a number of studies have adopted motion inertial measurement units (IMUs) in conjunction with mobile applications, VR, and gamification platforms in order to implement a biofeedback loop for patients involved in at-home rehabilitation following knee surgery, as described in [35], [36]. For example, Argent *et al.* [35] combined a calf-based IMU with a mobile application in which an avatar mirrors the user's movements in real-time, counts repetitions, and gives advice on the participants' technique at the end of the exercise. On the other hand, [36] relied on data from a single IMU to feed into a serious gaming platform offering feedback to the patients in relation to whether the performed exercises were accurately conducted.

In a knee rehabilitation context, [14] represents the best example of combining IMU and EMG data for identifying the recovery stages in ACL-reconstructed subjects during ambulatory and balance testing activities. Likewise, few studies have investigated the combination of EMG and EMS in knee rehabilitation. Boucher *et al.* [37] showed that a surface EMG-triggered EMS intervention improved knee range of motion in participants. As underlined in [38], although EMS and EMG-based biofeedback have been paired in different studies in literature, there is still a need for future research in the field.

In the last few years, researchers have also considered the possibility to adopt wearable systems besides the standard IMU-based technology for the long-term monitoring of joint kinematics. As an example, [39] investigated the use of a retractable string sensor which estimated accurately knee flexion/extension angles during locomotion at various walking speeds. On the other hand, Vargas-Valencia *et al.* [40] adopted a combination of IMU and polymer optical fiber (POF) integrated into a knee sleeve. Finally, a combination of MEMS and piezoelectric microphones (for joint sounds estimation), electrical bioimpedance sensors (for assessment of swelling), and IMUs was proposed in a prototype for robust knee joint health assessment [41]. However, while acoustic emission monitoring has shown potential of becoming a useful diagnostic tool for lower-limb pathologies, further research is still required to prove the feasibility for remote rehabilitation [42].

B. MARKET PRODUCTS

The market for wearable sensors has been massively growing in the latest years, and such technologies represent a suitable alternative to lab-based assessments thus enabling remote real-time objective monitoring in subjects involved rehabilitation. The global market for wearable rehabilitation devices was valued at $859.2 million in 2017. The market is expected to reach $3.3 billion by 2023, increasing at a CAGR of 25.4% through the period [43].

The number of products in the physiotherapy/rehabilitation market has been increasing consistently in the last years. There are a number of systems based on Kinect or similar technologies, which provide exergames and virtual therapists for remote monitoring in a number of applications (orthopedics, stroke, Parkinsons, etc.) and for several joints. Some examples are MIRA Rehab [44], Reflexion Health's VERA technology [45], or Jintronix [46].

However, the range of healthcare systems based on wearable sensors is even larger, due to the recent explosion of wearable systems in the medical market. Some examples are Riablo by Corehab [47], SWORD Health [48], or Hinge Health [49]. Those systems adopt a number of wearable sensors easily attachable via Velcro straps to the joints of interest, which are able to collect data from patients involved in a number of exercises and which are supported by mobile applications, also available to clinicians. Those products are generally based on motion sensors only, in order to keep their costs low, and are general-purpose, meaning they could be adopted for monitoring and evaluation of a number of conditions. Because of the requirement to be used for a variety of conditions, the number of exergames available in those systems tends to be quite large, thus increasing the overall costs of the platforms.

Knee-specific solutions are thus considered more suitable from a cost-perspective for patients following sport-related knee injuries/surgeries. For this specific case of interest, a wide variety of products have been proposed on the market. The products provided by Claris Healthcare [50], Breg [51], Consensus Orthopedics [52], and 270 Vision (BPMphysio) [53] are similar and propose small-size wearable IMUs attachable to the lower-limbs together with mobile apps for both patients and clinicians. A similar concept is illustrated in products such as Orthelligent KNEE from OPED [54] which uses a single motion sensor on the calf. It is evident that all the products focus only on IMU-based solutions to deliver low-cost and easy-to-use systems; however, this limits the number of insights that clinicians can rely on for their assessments, as well as the possibility to implement remote treatments and interventions (i.e., gait retraining) which are based on the implementation of a biofeedback mechanism.

A possible winning approach, which could minimize some of the indicated challenges, could be the development of a multi-sensor wearable platform which is based on general users' requirements identified and described in Section III.

III. SYSTEM REQUIREMENTS

In the following section, the requirements which the system should satisfy for the remote monitoring of knee rehabilitation are identified and commented.

Based on a meta-analysis of 20 publications available in literature [55], a series of users' needs regarding the tele-rehabilitation of knee conditions has been taken into consideration in this work, which can be summarized into five key areas informed by clinical advisors and end-users:

a. Sufficient and comprehensible information about generic and condition-specific matters;
b. Tailored exercise plans considering patients' individual circumstances;
c. Recovery monitoring based on data supplied by patients (functional tests and questionnaire surveys);
d. A virtual community of patients;
e. Support for patient-doctor interactions.

Moreover, Spasic *et al.* [55] also broke down those users' needs into component tasks and a prioritized set of feedbacks, including:

i. Have access to both general and condition-specific information;
ii. Have access to questionnaires and functional tests to allow patients to track progress;
iii. Receive notifications about upcoming tests;
iv. Visualize results and allow the comparison against other patients' averages;
v. Visual feedback on progress;
vi. Knowing what tests a patient will have to do and when;
vii. An exercise plan with detailed exercise descriptions;
viii. Be able to talk to clinicians;
ix. Specify patient's demographic and medical details to get personalized content;
x. Use the system properly: register and delete the account, help on how to use the system, and a frequently asked questions (FAQs) section.

Furthermore, when considering quantitative feedbacks on progress tracking with the goal to provide all-around knee-related information on the patient's biomechanics and muscle condition, it is important to incorporate a number of multi-modal sensor technologies. These include IMUs to provide details on kinematics, sensors located on all the relevant muscles on the lower limbs able to measure the activation signals (EMG), and technologies able to electrically stimulate (via EMS) specific muscles which are heavily involved in the rehabilitation process, in the event the clinicians require such activation.

Real-time analytics are expected to be included on-board to determine joint angles and muscle activation signals. Therefore, it is expected that a patient-centric system is able to gather movement and other data via the sensing technologies interfaced with a central processing unit, to process, contextualize and analyze the data, ideally in real-time, thusly transforming it into information (according to the edge computing concept), and to wirelessly transmit the information via a predefined network architecture to where it can be processed further and/or visualized. The system should provide real-time feedback to the wearer regarding movements and specific exercises (for example, visually and/or via haptic technology), and potentially include virtual games to increase motivation and engagement.

Finally, based on feedbacks collected from several stakeholders (Section IV), it is indicated that the system should be wireless (and adopting standard wireless technologies, such as Wi-Fi, Bluetooth, etc.) to guarantee ease of use, be battery-powered with a rechargeable battery, and with the battery supporting system operation for a minimum of 2 hours before being charged (expected charge time of approx. 2 hours) to cover the maximum time spent by patients in a rehabilitation session. The wireless communication should have a range of $\geq$ 10 meters indoors (to cover typical indoor environments, such as homes or clinics) and throughput high enough to enable an overall end-to-end latency $>$5 Hz (to guarantee that the visualization on the mobile app moves in real-time with the patient without any time lag). The system should have sufficient processing capabilities and memory to potentially perform the required calculations on-board and for on-board data storage. The IMU sensors should have a sampling frequency $>$ 30 Hz to ensure sufficient kinematics data are collected, and be small-size, low-noise and low-power. We propose a configuration of two IMUs placed on the thigh and calf, EMG sensors placed on quadriceps, hamstrings, and calf muscles, and EMS on quadriceps and hamstrings. Biocompatible materials and limited size should be also considered, as well as ease of use and comfort. All the present needs have been taken into account, together with industrial design considerations, when developing the hardware and software components of the system. The smart system should support rehabilitation from pre-surgery to the final post-surgery phase and return-to-sport.

In order for the implemented wearable platform to satisfy all the requirements previously stated, an industrial design process (explained in Section IV)) is carried out, which resulted in the generation of a system architecture and the related block diagram (analyzed in Section V).

IV. INDUSTRIAL DESIGN CONCEPT

The authors interacted with a third-party industrial design partner (Design Partner, Bray, Ireland [56]) for engaging with end-users (e.g. physios, clinicians, and athletes), collecting their feedback, and developing a suitable concept and solution which could fulfill most of the identified user needs. A two-part solution involving a thigh strap and a calf cuff has been proposed as it allows for easy don-doff without the need to remove clothes and does not restrict knee movement during rehabilitation exercises. The sensing technologies met the user needs as defined in this Human Factors Evaluation process and are placed on designated areas on the lower limbs. A breakdown of the proposed sensor positioning is shown in Figure A.1. The main unit is worn on the thigh to collect data from the quadriceps-hamstring muscles, while the smaller unit is worn on the calf to monitor calf muscles. Moreover, both units present a processing unit in conjunction with an IMU, so that joint angles and movement-related parameters (e.g., smoothness) can be estimated.

Bluetooth wireless communication is used to synchronize the data from the separate units.

The design of the overall garment concept is illustrated in Figure A.2 (as a sketch – right, and as 3D rendering - left), while Figure A.3 shows the proposed inside of the garment in detail. The design foresees the use of special hypoallergenic fabric and silicon grip to improve garment grip when worn. An example of the processing unit connection with the garment is instead shown in Figure A.4.

Finally, given the importance that end-users' motivation and compliance have on rehabilitation process, a sketch and a video on possible visualization approaches for progress tracking, performance monitoring, and rewards were also proposed (Figure A.5 and Supplementary Material 1, respectively). Figures A.1-A.5 are available in Appendix A.

V. SKYRE ARCHITECTURE AND BLOCK DIAGRAM

The following section deals with the description of the system architecture for the project.

Figure 1 shows a block diagram of the SKYRE system. As identified in the users' requirements phase, the system adopts two IMUs on the lower limbs, EMG sensors located on relevant muscles in the lower limbs, and EMS to electrically stimulate specific muscles (placement described in detail in section VI). The two units on the thigh and calf are battery-powered and independent from the perspective of power management as well as from the computational point-of-view, as they have separate microcontrollers and power supplies and management circuits. The two units are wirelessly synchronized and one of these units can interact with the mobile app running a smartphone/tablet for data visualization. The mobile app is used by the patient to communicate and retrieve information from the wearable device, and to receive guidance as regards their rehabilitation from a humanoid avatar which replicates the user's movements in real-time during each exercise. Also, a score metric (developed to establish the quality of the performance based on the comparison to standard patterns in healthy subjects available from a public dataset) is given at the end of each exercise. The patient has access on the mobile app to the entire history of every rehabilitation exercise. Separately, the data is also transferred to the cloud to allow clinical experts to access them remotely on a web portal, thus allowing them to monitor multiple patients' results on a dashboard and at the same time, evaluate their progress, and tailor the rehabilitation protocol for each patient.

The designed and realized hardware platform will be described in Section VI, while the software platform is shown in Section VII.

VI. HARDWARE PLATFORM

As evident from Figure 1, the hardware platform consists of two parts. The Secondary unit is worn on the calf and includes an IMU and four EMG electrodes which monitor the gastrocnemius muscles (medial and lateral head). The unit also includes a Bluetooth 5.0 module for communication with

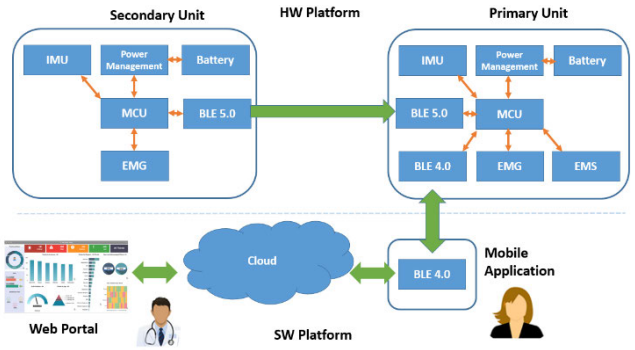

FIGURE 1. SKYRE system architecture.

the Primary unit, a microcontroller, and battery management circuitry. The EMG sensors are fully embedded into a textile sleeve. The wiring of the electrodes to the electronic board consists of wires connected to the electrodes with conductive epoxy. The Primary unit is worn on the thigh and controls the communication with the Secondary unit as well as the mobile application on the user's smartphone. The Primary unit therefore includes an IMU, two EMS circuits and four EMG sensors, a Bluetooth 5.0 module for communication with the Secondary unit, a microcontroller, battery management, and a second wireless module (Bluetooth 4.0) for communication with the mobile device.

The IMU adopted by both Primary and Secondary units is a 9DOF MPU-9250 from InvenSense [57] as it combines a 3-axis gyroscope, 3-axis accelerometer, and 3- axis magnetometer in a 3 x 3 x 1 mm package. The microcontroller selected for both units is the STMF417IGH from ST Microelectronics [58] as it combines low-power and high-performance and is supported by an ARM®Cortex®-M4-based 32 bits architecture, single precision floating point unit, up to 168 MHz operating frequency, up to 1M FLASH and 196 Kbytes of RAM. The units are purely battery-operated. A 604040 Li-ion rechargeable battery was used. The charging circuit is embedded in the units and a type-C USB cable is used for the purpose.

The Primary device also includes a haptic feedback component, which could be adopted for real-time biofeedback or for gamification purposes. An Eccentric Rotating Mass (ERM) actuator was adopted to this purpose as it represents the most mature haptic technology in the market. The DRV2605 [59] was adopted for this particular system. Additional features of the system include a microSD card for local data storage, 4 extra bright LEDs for user feedback, and touch surface to interact with the devices (start/stop, on/off).

The PCB boards size with the enclosure are 90 x 60 mm and 70 x 80 mm, for the Primary and Secondary unit, respectively [60]. Power consumption reaches 300 mA for the Primary board and 42 mA for the Secondary board (at 100% duty cycle). The PCB boards are enclosed in two custom designed 3D-printed enclosures attached to the garment.

Eight electrodes have been adopted to measure the EMG signals generated by muscles of interest (i.e., rectus femoris,

vastus lateralis, semitendineous, and biceps femoris). Those electrodes were placed according to SENIAM guidelines (http://www.seniam.org/). Surface EMG have been adopted for both Primary and Secondary units. An amplifying circuit has been designed to capture the EMG signal. The circuit comprises several stages: A differential amplifier for the signal acquisition (I stage), amplification (II stage), 100 Hz filtering (III stage), rectification of the signal (IV stage), smoothing stage (V stage), final inverting stage (VI stage).

On the other hand, the EMS circuits stimulate the quadriceps and the hamstrings and 4 electrodes were used. Similarly, to EMG, dry electrodes are adopted for EMS. The circuit required to drive the EMS electrodes used a haptic driver (DRV8662) adapted for this project. EMS impulses can reach over 100 Vpp and have different shapes and durations, and the DRV8662 [59] allows the generation of the required voltages and the required shapes of the output waveform.

Various types of electrodes available were considered as option for the EMG and EMS interfaces, including PEDOT:PPS electrodes (which are actively gaining popularity recently), knitted textile electrodes, and also woven fabric (such as nylon ripstop). Finally, nylon silver-coated woven fabric Shieldex Bremen [61] was used as a base for textile electrodes as it shows optimal performance characteristics for the use case envisaged [62], [63], [64], it is safe to use in contact with human skin, even in the case of prolonged contact, and shows suitable electrical properties.

The impedance characteristics of the electrode-skin contact is highly dependent on how hydrated the skin is. To avoid impairment of conductive fabric electrical properties (as highlighted in [65]), instead of coating the back of the electrode [66], a thin polymer sheet was glued onto the base fabric. Then, a slightly bigger piece of conductive fabric was glued onto base fabric using textile glue, so that only edges of the conductive fabric were glued and the majority of the electrode surface had a waterproof layer underneath.

Thin stranded wires with reinforcement thread incorporated were attached to the electrodes by sewing them with stainless steel conductive thread. The resistance of the textile electrodes, measured between the end of the 20 cm wire and the distant edge of the conductive fabric, averages 1.8 Ohm.

To simplify the prototyping process, mass-produced commercially available shorts were chosen as a base layer for the garment. Electrodes were sewn together in pairs and then were additionally strengthened with several lines of machine stitching to prevent the conductive fabric stretching and changes in inter-electrode distance during movements. A layer of felt was sandwiched between the electrodes and the base shorts to act as padding to help reduce motion artifacts (Figure 2, top) in the data signals.

Connective wires were threaded through the fabric from the inner layer to the outer layer to improve the wearer's comfort and were attached to fabric using zigzag stitches into respective place. A spare length was left to allow the free stretching of fabric when worn (Figure 2, bottom). The same procedure was repeated for the Secondary sleeve. Sleeves

FIGURE 2. Primary sleeve - inner layer (top) and intermediate layer (bottom).

FIGURE 3. Primary and Secondary sleeve - general view.

were connected to the inside of mass-produced athlete's running shorts to provide optimal fit and ensure stable skin-electrode contact since inner layer fabric is relatively thin.

The overall appearance of the second prototype [67] (female, size-small) is shown in Figure 3.

VII. SOFTWARE PLATFORM

The implementation of the software platform is described in this section. The software platform mainly consists of three parts: the firmware that is used to communicate between

Primary and Secondary units, the mobile application for the patient users, and the web-based application used by the clinicians for remote assessment. All these parts are separately discussed in the following subsections.

A. FIRMWARE

The Secondary unit wirelessly streams the collected data (IMU and EMG envelope measurements from 2 muscles) to the Primary unit via Bluetooth 5.0. This communication occurs every 30 msec. The Primary unit collects the data received from the Secondary unit and synchronizes them with its own data (IMU and EMG measurements from 4 muscles) forming a single packet for transmission to the mobile device. A sensor fusion algorithm is implemented on-board the Primary/Secondary units to calculate the 3D orientation (expressed in quaternions) of the two limbs. These quaternions are appended to the data packet defined by the Primary unit and transmitted wirelessly to the smartphone app via Bluetooth 4.0. A standard approach based on the well-known algorithm published by Madgwick *et al.* [68] has been chosen as it provides a good trade-off between accuracy and computational complexity. The algorithm was developed in C and ported on the microcontroller on the Primary/Secondary units and is able to run on the embedded system.

The Primary unit can also accept incoming data packets from the mobile application to activate and configure haptic feedback and muscle electro-stimulation.

In more detail, the two microcontrollers in the Primary and Secondary units work in parallel. The Secondary unit's microcontroller carries out the following tasks:

- Reading from IMU values,
- Calculate the associated quaternions,
- Communicate with the Bluetooth 5.0 module (Via UART);

The Primary unit's microcontroller performs the same tasks and, in addition, also carries out two more tasks:

- Electronic Muscle Stimulation (EMS)
- Communication / management of the Bluetooth 4.0 chip

The overall packet sent from the Primary unit to the mobile app includes the following data:

- 3-axis accelerometer, gyroscope, magnetometer values (from Primary unit),
- 4 channels sEMG values (from Primary unit),
- Quaternions associated to IMU data (from Primary unit),
- 3-axis accelerometer, gyroscope, magnetometer values (from Secondary unit),
- 2 channels sEMG values (from Secondary unit),
- Quaternions associated to IMU data (from Secondary unit).

Overall, the packet formed by the Primary unit is 160 characters/bytes (e.g., 32 elements of 4 characters separated by a comma). Given that the communication speed via UART between microcontroller and Bluetooth chip is equal to 115200 bps, the maximum frequency f_{max} is then equal to 90 Hz, which is higher than the target frequency of 30 Hz considered for the communication between Primary unit and the mobile app.

The synchronization process between Primary and Secondary units is described in detail in Appendix B.

B. MOBILE APPLICATION

The SKYRE mobile application allows for the remote monitoring of the rehabilitation progress as well as providing feedback to the patients in order to increase the engagement of the patients in their rehabilitation. A key factor for the application is relying on a flexible data model that enables the clinicians to customise the recovery plan for each individual. The developed internal data model allows customising the stages and exercises for each patient based on their physical conditions at any time during the recovery. Overall, the goals of the SKYRE mobile application are to:

- Provide the exercises according to the stage of recovery of the patients;
- Validate the exercises performed by the patients;
- Compare individual progress and provide feedback to the patients;
- Report to physician about the progress of the rehabilitation;
- Keep the patient motivated and engaged;
- Provide a bi-directional communication channel between patients and clinicians.

The mobile application has been developed on Android operating system (OS). The application is written in Java and was designed to work for Android smartphones having a modern screen size (+5 inches).

Fundamental aspects of the mobile application development, such as app structure, screens, data model, time sessions, and exercise timeline and view are discussed in the following subsections.

1) APPLICATION STRUCTURE AND MAP

The app is based on five main modules: *Home, Knowledge Base (KB), Recovery Tracker, My Self-Care Plan and Support*, as suggested in [55]. Details on each of those modules are illustrated in the subsections below.

The app has been designed to operate into five depth levels, as shown in Figure 4. The blue boxes indicate the activities/screens while the green ones show the options menu.

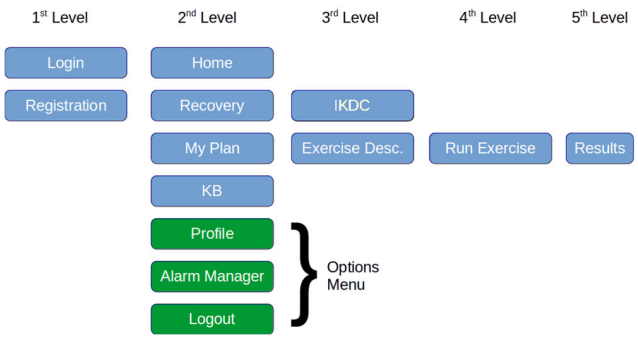

FIGURE 4. Depth level.

2) SCREENS

This section shows and explains the activities in the current version of the app.

a: LOGIN/REGISTRATION

If the user has not yet registered with the SKYRE application environment, the login screen (Figure C.1) will continue to appear asking for username and password. In order to create a new account, the user has to tap on the ''Register'' link that appears on the login screen. The registration process (Figure C.2) asks for the basic personal information required to customize the recovery plan by the clinicians. In the same registration process the new SKYRE credentials are required (user name and password).

b: HOME

The *Home* displays some basic information about the app, and links to the knowledge base (Figure C.3).

c: RECOVERY TRACKER

The *Recovery Tracker* component provides access to an interactive tool designed to help registered patients assess their recovery progress over the course of rehabilitation (Figure C.4). Two types of patient-reported outcomes are collected: subjective and objective. Subjective data are based on the IKDC questionnaire, and other measures (pain, knee circumference, other symptoms, etc.). The IKDC questionnaire is shown automatically to the patient periodically through the stages. Once a patient completes a test, the system computes a score, which is visualized on a plot so that the patient can track their progress over time.

d: MY SELF-CARE PLAN

My Self-Care Plan aims to help patients to achieve an optimal functional outcome in terms of joint pain and/or swelling, knee flexion and extension, gait pattern and stability, muscle strength, proprioception, balance and coordination. To this purpose, this module contains an exercise-based rehabilitation program divided into three phases (early, intermediate, and advanced physiotherapy), followed by the final phase (return to normal activity), and a pre-surgery phase. This program has been defined according to clinically available recommendations and feedbacks [69]. No timelines are associated with each phase; indeed, progression depends on completion of the current phase, before advancing to the next one, with each phase characterized by its own aims, exercises, and progression criteria [69]. A patient can only progress to the next phase if all the progression criteria are met and the physiotherapist agrees with that. Each exercise is shown on the app containing a video or an image and a short description.

To allow a user to easily access and record information, the app provides a selection of appropriate exercises as the patients progress through the rehabilitation phases, while the app allows them to keep a diary of exercise activities as they actually do them at home. The app's functionality includes exercise selection, access to exercise instructions with a video and brief description, logging an exercise together with pain and effort required for its completion as well as any other comments, and tracking progress by monitoring pain and effort over time.

e: KNOWLEDGE BASE

The *Knowledge Base* menu (Figure C.5) offers information related to the recovery of an ACL grouped into four categories. The content of the four categories is divided across:

- ''General Information'' section, which contains information about the aims of physiotherapy, types of rehabilitation, rehabilitation goals, etc.
- ''Before'' and ''After'' surgery section, which provides answers to common questions patients are concerned about.
- ''Rehabilitation'' section, which provides information for the patients to understand the importance of the positions of the exercises.

3) DATA MODEL

This section describes the data model structure, e.g., where information is stored, and where data can be queried and visualized on the screen. The data model structure also allows prepopulating meta-data to be used by the application in certain activities. For instance, there is a predefined list of stages and exercises, and each exercise is filled with meta-data that define it (i.e., name, description, video sample, how the exercise has to be performed in terms of repetitions, resting time, joint angle's thresholds, score validation algorithm). Another data structure set used in the app is the current stage of patients' recovery. This structure allows the app to keep track on the patients' activities: stage, session data, e.g., start date and time, elapsed time since it started, exercises performed and current exercise, values from the subjective questions (IKDC), and exercises' scores. The results of each exercise are stored using a data structure available into the device.

Datasets, instead, are composed by identifiers, sessions and exercises. Two identifiers are used, for the rehabilitation stage and for the set of sessions. Each session contains:

- Timestamp range (to control when a session has been started and finished),
- Subjective question results (values for the questions about pain, knee size, and effort required for an exercise),
- Set of exercises.

Each exercise contains:

- Timestamp range (to control when a session has been started and finished),
- Exercise identifier,
- Score.

This data structure allows new exercises to be included, as well as sessions and stages; therefore, it is flexible and scalable. A graphical representation of the data structure is shown in Figure 5.

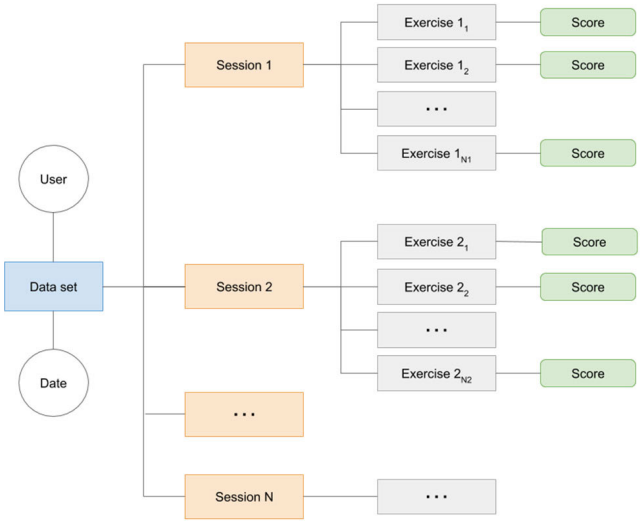

FIGURE 5. Data model.

4) RECOVERY SESSIONS

A rehabilitation process is composed by multiple sessions, and sessions are composed by a series of exercises. The app is set up to control both exercises (repetitions, timing, etc.) and sessions.

When the patient starts the session, she/he has to go to *My Self-Care Plan* and tap the "Play" button. However, before the exercises can be performed, two subjective questions are introduced:

- *How painful the previous session was?*
- *Please input the injured knee circumference in cm.*

The answers are used to generate cumulative charts and displayed in the *Recovery* section. After the questions are answered, then the patient can tap on the first exercise (highlighted in blue). In addition, the data model allows a patient to perform the same session "n" times per day (minimum of 1). This can be customized for each patient. *My Self-Care Plan* shows the current stage, the current session and its status (active, inactive, finished) and the actions that can be performed (Play, Finish), and below the list of exercises within the current stage and their status (pending or done). At the top bar there is an information button "i" which displays all stages and their exercises and it is used for informational purposes only. Figure C.6 shows a screen of the activity.

When the patient taps on any grayed exercise, the view with its description is shown. However, if the patient taps on the highlighted exercise (blue background) there is a pop-up coming up showing two options: Information and Start. This is to allow the patient to check the exercise before it starts. If the patient taps on Information the app shows the description of the exercise as in tapping the "i" icon on the top navigation bar. If the patient taps on the play icon, then a countdown starts. Afterwards, the exercise view is presented. At the end of the exercise, a new view is shown with the results of the exercise performance.

At the bottom of the view the patient can go back to *My Self-Care Plan* or perform to the next exercise. A patient can finish a session by tapping on the racing flag icon. When all the sessions are finished, the session label on the screen is set to "Finished" and no more sessions can be performed for that day. Session results are shown in the *Recovery* tab.

5) EXERCISES TIMELINE

A Timeline view of stages and sessions has been implemented into the app (Figure C.7). This is a functionality that allows the patients to better understand at which point into the recovery plan they are. They can see which stage they are in and which sessions have been finished and how many other they still need to accomplish. Further, the information provided in this new view links to the sessions' charts. Filters to the Timeline view can be applied by tapping on the dates shown on the top bar of the view. The Timeline view is automatically generated and updated along with the progress of the patients. This view can be accessed by tapping on the Recovery bottom bar menu. On the bottom part of the view the patients can find two buttons bringing them to perform the IKDC Test, and the charts based on the subjective questions entered by the patient into the app and described in the *Recovery Sessions* section.

6) EXERCISE VIEW

This is the view presented to the patients when starting the exercise. The view is divided into two blocks: meta-data and 3D scene. The meta-data shown to the patient is composed by the details on how to perform the exercise. This information is static and it is also available before the exercise starts. The 3D scene presents a fitted living-room having a humanoid replicating the users' real-time activity of the lower limbs based on the quaternions provided by the system. The top part of the scene contains four colored circles showing the current series, total repetitions detected, last repetition score, and last repetition joint angle. The values of those circles are modified in real-time during the exercise execution. At the left-hand side of the scene there is a vertical bar which fills itself along with the patient's movements. The vertical bar let the patient visualize the minimum and maximum angle the exercise is expected to be performed. White labels with figures (change depending on the exercise) on the top and bottom of the vertical bar indicates those values. The thin yellow line indicates the real-time angle in degrees, where the leg is positioned from the ground. If the figure on the labels is in light green, it means that there is a repetition ongoing. If the patient's leg goes beyond the limits, the green vertical bar becomes red and beeps until the leg gets back to the expected angle degrees range.

When the exercise starts, the application is ready to read the data points sent by the Primary unit. When the patient starts moving the limb, then the humanoid in the scene recreate the movement. All the tasks performed in real-time are described as follows:

- Receive real-time data from the Primary unit,
- Detect, count and update the number of repetitions,
- Develop the score for the repetition,
- Update the vertical bar,
- Move the lower limbs of the humanoid.

Figure C.8 shows two examples of the visualization tool developed for a hamstring curl exercise and a straight leg raise. At the end of the exercise, the app automatically redirects the patient to a new view showing the results of the exercise performance. In addition, the final score is shown and a customized feedback message is attached to the view based on how well the patient performed the exercise (two examples shown in Figure C.9). Figures C.1-C.9 are available in Appendix C. Details on how the system obtains a final score for an exercise are presented in Section VII.C.

C. REPETITION COUNTING AND SCORING MECHANISM

The mobile app includes a repetition counting mechanism described in the following paragraphs. The algorithm is based on the joint angle data measured by the IMUs. Given the cyclical nature of the repetitions performed for a specific exercise, the algorithm adopts a state-machine approach which is characterized by the minimum and maximum threshold values of the knee joint angle. The correct pattern of minimum and maximum values identifies a proper repetition execution and its counting.

When the patient performs an exercise, data points are sent to the app from the Primary unit. Then, the app starts looking for repetitions verifying chunks of data points in the joint angle signal obtained from the orientations of thigh and shank. Figure 6 shows an example with three detected repetitions.

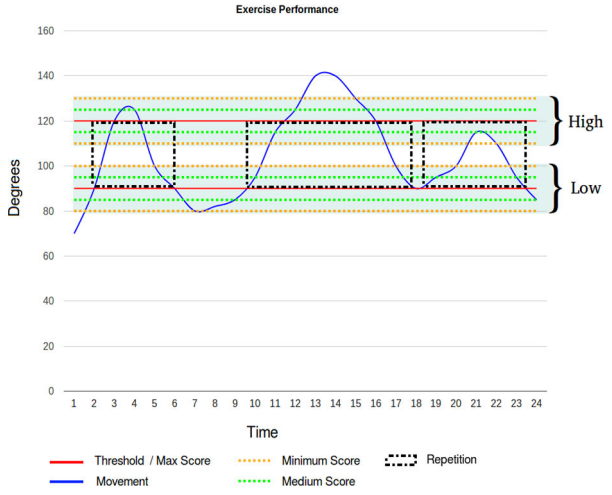

FIGURE 6. Example of repetitions counting.

In detail, an array of three positions must be filled in a particular order. When the array is filled, the readings from the leg movements count as a repetition. The contents of the array must follow the convention and the following order: Position 0 - MIN, Position 1 - MAX, Position 2 – MIN. Those values (MIN, MAX, MIN) are pushed to the array when the minimum and maximum angle degrees of the performing exercise are reached by the patient. If the patient follows the pattern, a repetition is achieved and counted as such by the app, so the app knows when to stop (e.g., max number of repetitions per exercise reached). Any other order detected makes the movement of the leg to not being counted as a repetition and the app restarts detecting repetitions. In summary:

i. The app checks if the patient is in a repetition scenario (e.g., current joint angle value is in between the pre-defined minimum and a maximum thresholds – namely MIN and MAX),
ii. If the current joint angle equals or is less than the MIN angle plus a margin of 2 deg, and the last detection was different from MIN, then the app adds MIN to the array (e.g., first condition is met),
iii. Once the first condition is met, the same approach is used for the MAX value (second condition), and once the second condition is met the same approach is re-used for another MIN (third condition),
iv. When the array has three elements the order of a repetition has been reached,
v. A repetition is counted and the array is cleared for the next repetition.

A number of approaches could be used to evaluate the "quality" of the movement of the detected repetitions, such as Dynamic Time Warping [70] or Hidden Markov Models [71]. For this system the implemented exercise scoring algorithm is based on the Gait Deviation Index method suggested by Schwartz and Rozumalski [72] and is as follows:

- The measured joint angle for a repetition for a specific exercise is taken into consideration,
- A reference pre-populated joint angle curve of 100 data points (obtained from a distribution of healthy subjects replicating the exercise) is taken as a static variable already available in the mobile app. Moreover, also the mean and standard deviation (μ and σ) of the healthy subjects' distribution from their mean are already available in the app as variables for each exercise,
- Both the measured and the reference joint angle curves are reduced to the same number of data points (100 in this case) via the Ramer-Douglas-Peucker method [73],
- Calculate the Euclidean distance d between the two curves, and the natural logarithm of this distance l,
- Standardize the obtained value using the mean and standard deviation of the healthy subjects distribution ($z = (l - \mu)/\sigma$),
- Calculate the final score as $score = 100 - 10 * z$. As a result, the value is finally reported on a scale such that a score of 100 is perfectly in-line with the healthy subjects' curve and, the larger the distance from 100 the larger the difference between the healthy subjects' reference and the performed repetition.

D. CLOUD INFRASTRUCTURE AND WEB DESKTOP APPLICATION

The ICT system includes an online cloud infrastructure which supports the mobile application as well as a web portal associated with the platform. The cloud infrastructure incorporates a web server and a relational database (DB). The functional web portal prototype has been designed, developed

and deployed online to allow physiotherapists to manage and monitor their patients' recovery plan.

The platform's architecture counts on an online virtual machine that includes a database and a web server with a RESTful API service. The latter ensures a secured mechanism to exchange data between the platform and the clients (mobile app and web portal) using the Authentication module and data travelling over an SSL certificate installed in the web server. The SSL certificate allows communications to be encrypted in both directions from/to the server. The data wrapper used for communications between the clients (users) and the API (server) is JSON, which is a standard notation format for RESTful services. The DB is only accessible through the API, so that it is not exposed to the public in other way. Figure 7 shows a visualization of the current implementation of the architecture.

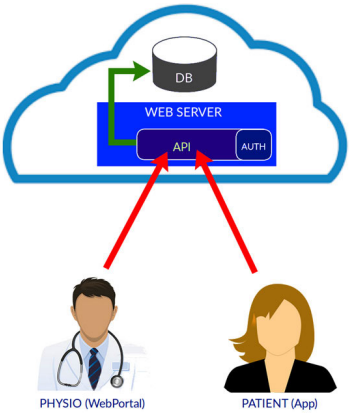

FIGURE 7. ICT architecture.

Both physiotherapists and patients are connected to the platform using the same entry point: a RESTful API service developed specifically to support both kinds of users. Within the API there is a module called AUTH that verifies the user credentials and authorizes access to the platform. Finally, to comply with the GDPR European directive, the cloud infrastructure is set up physically in Ireland (EU territory).

The following subsections describe in details the cloud infrastructure (in term of server services, API, authentication, encryption, and database) and the web portal.

1) SERVER SERVICES

a: API

In order for the app and the web portal to interact with the cloud infrastructure and consume its resources (i.e. queries to the database), a RESTful API has been designed and developed along with authentication methods to secure accessing the platform to only registered users. The API has been developed based on PHP Slim Framework (*http://www.slimframework.com*). The API is divided in two main folders both containing configuration files as described above:

- API: where the main entry point, the authentication middleware, and mapped routes reside.
- Services: where the entities, DB operations (inserts, updates, etc.), physio and app service along with utility functions (mail, cryptography, filters,...) reside.

i) MIDDLEWARE AUTHENTICATION

The API authentication module is a middleware software (AUTH module in the architecture) that verifies the user credentials and authorizes access to the platform. This middleware is an independent component of the API and it is executed into the entry point to verify that the requester of the API service has the tokens generated by the login process. This ensures that the requests are made from a logged-in user. This module uses the DB to do the verification when there is a login request and, if it succeeds, it generates an APIKey token and stores it on the logged user table. Then, any request made by that user has to incorporate the APIKey by adding a custom HTTP header, which is an added meta-data. When that logged user wants to consume any API service, the middleware validates that the user has a valid APIKey token in the request and in the DB. Depending on the requested API service, the requester (web portal or mobile app) have to add extra HTTP headers with such information. Otherwise, the authentication middleware will produce an error and the request will not be satisfied.

The authentication middleware verifies that the headers exists, that they are not empty, and that their content matches them against the DB logged in user's table. If all are satisfied, then the request can be served to the requester. Other API services require other custom HTTP headers.

This module also filters which service the requester can have access to, i.e., a physiotherapist will not be able to login into the mobile app using the same credentials of the web portal, and vice-versa, patients will not be able to log in into the web portal using the app credentials. This restriction is in place on purpose as the two services (app and web portal) are exclusive for their expected users (physiotherapist and patients).

After setting the application and inject the API services, the authentication middleware is required as the URL mapped routes will require the authentication mechanism.

ii) ENCRYPTION

The scripting language of PHP v7.x used to develop the API comes with a built-in library called *Sodium* (*https://www.php.net/manual/en/book.sodium.php*), which allows developers to encrypt sensitive data without using external libraries. *Sodium* uses AES-256 encryption algorithm. The API encrypts and decrypt all sensitive data of an individual (physiotherapist of app user). Data is stored encrypted but served to the users decrypt. The decrypt function is also incorporated into the API and transforms the characters into their original data representation, which the API will return to the user interface.

b: DATABASE

The data model implemented into the DB describes how data is split across multiple tables and how they relate to each

other. For patients, the current model makes no changes for them in any way, so the model allows to store and keep track of their personal details, recovery plan status and reports of the results of the activity (i.e., exercises, sessions, subjective questions, IKDC results). However, this model for physiotherapists allows them to:

- Manage and monitor their own pool of patients, their recovery plan status and activity reports. Neither the list of patients nor their data is shared with other physiotherapists in the platform,
- Create and customise recovery plans (stages and exercises). Custom recovery plans are not shared in the platform with other physiotherapists,
- Create and customise exercises. Those custom exercises are not shared with other physiotherapist in the platform.

2) WEB PORTAL

A web portal prototype for physiotherapist has been designed and implemented as part of the platform. Through the web portal physiotherapists are able to manage their patients' evolution using interactive charts, create and modify custom recovery plans and exercises. The web portal has been developed using Vue Javascript Framework (https://vuejs.org/). In order to communicate with the server's API, the Axios library (https://github.com/axios/axios) is used. To handle dates the Moment.js package (https://www.npmjs.com/package/vue-moment) is used.

Users of the web portal are registered by the authors in order to manually control who can have access to the platform. The process to create a new web portal user is by inserting a new record into the DB's table. The fields that have to be filled in are:

- Name: name of the user,
- Username: user name to be used in the login validation process,
- Password: encrypted password using AES-256,
- Email: unique email to be used when a recovery password is required.

The web portal is divided into three main options: Home, Patients, and Recovery Plans. The login page, though, is firstly visible. The Login page (Figure D.1) is the entry point of the web portal. After the user has successfully logged in, the Home page (Figure D.2) is shown with a welcoming message. The Patient's menu (Figure D.3) option lists all the patients associated with the physiotherapist user. At the first glance, the user can view name, surname, recovery plan, stage of the patients, along with username, email and icon actions: View Analytics, Account, Profile. The Analytics icon pops up a new screen with the following list of charts: IKDC, subjective questions (answered by the patients as indicated in section B.4), and exercises' results. All charts are interactive. Figure D.4 shows an example of the IKDC chart and of the Exercise results chart.

In the main list of patients, a button ''New Patient'' allows the physiotherapist to create a new patient. The process (Figure D.5) is split into two steps:

i. Create the account of the patient which sets username, email, recovery plan and current stage,
ii. Create the patient's profile which sets the personal details.

The Recover Plan option allows the physiotherapist to create and customize recovery plans and exercises. The screen shows its content hierarchically so they appear only when the patent content is on. This is automatically done by the application. The hierarchy is as follows: Recovery Plan > Stages > Exercises > Exercise's detail. Figure D.6 shows the layout of the content's hierarchy and its action.

The user can create and edit Recovery Plans using the buttons below its box (Edit and New). In order to view the stages of a Recovery Plan, a click on the name of the Recovery Plan displays the next box: Stages. The box of Stages shows one button per stage. To view the exercises per stage the user has to click on the button (i.e. Stage 1). Afterwards, the box of Exercises for that stage is displayed. The list of exercises associated with a stage is shown as buttons in a new box. Below the box the physiotherapist can then take two actions: Add or Delete exercises. By clicking on the ''Add'' button a new exercise can be added to the stage. A new pop-up window appears with a list of pre-populated exercises from the system repository of exercises. Figure D.7 shows the pop-up with the list of exercises. Moreover, the user can create a completely new one by pressing the ''New'' button on that pop-up window. This creates a new form where the physiotherapist can then fill in the meta-data of the exercise. It is completely up to the user to input the required information. Figure D.8 shows the ''New Exercise Definition'' form.

Back to the Exercise box, if the physiotherapist wants to remove one exercise from the state, a click on ''Delete'' shows a pop-up window with the current list of exercises and a checkbox to select which ones are to be deleted. The details of an exercise can be viewed and edited by clicking on the Exercise button from the Exercise box. Once a button in that box is clicked, a new box appears with the content, description and actions for that particular exercise. Figure D.9 is a zoom of the details of the straight leg raise exercise. The screen shows the name of the exercise, its description (which can include HTML tags to embed Youtube videos for demonstration, for example), and a set of colored slices for the meta-data of an exercise (repetitions, sessions, minimum score, minimum and maximum angle, etc...). The information related to the exercise can be edited by clicking on the ''Edit Exercise'' button, which opens up a new pop-up window with the pre-populated form of the exercise (Figure D.10).

Figures D.1-D.10 are available in Appendix D.

VIII. VALIDATION

The present Section discusses the validation of the different technology blocks of SKYRE against gold-standard technologies, with particular reference to the IMU, EMG, and EMS features. The study received approval by the Clinical Research Ethics Committee (CREC) of the Cork Teaching

Hospitals at the University College Cork (Reference Number: ECM 4 (p) 13/08/19 and ECM 3 (u) 12/11/19).

A. GENERAL SYSTEM

The overall system has a throughput of 30 Hz and allows operation for a minimum of 2 hours. Two videos showing the system in function are available in Supplementary Material 2 and 3.

B. KNEE JOINT ANGLES

The Range of Motion (RoM) obtained by the developed system is compared against a gold-standard technology. Ten healthy volunteers from the university population were recruited via electronic advertisement (7 males; mass 71.8±13 kg; age 28.7±3.6 years; height 173.3±8.3cm). Participants were excluded if they reported any previous musculoskeletal disorder, pain or discomfort. Recruited volunteers attended a single session in which 10 Prime-13 Optitrack motion capture (MoCap) cameras were used as gold-standard. Each participant was fitted with the developed system. Sixteen retroreflective, 14mm, spherical markers were also affixed onto the skin as per the lower body Plug-in-Gait model (i.e., on the anterior and posterior superior iliac spine, thighs, knees, shanks, ankles, heels and toes of both the left and right lower limbs). The MoCap and wearable systems were sampling at a rate of 120 and 30 Hz, respectively. Data from the implemented system were streamed wirelessly and saved to a computer device. Participants were asked to perform at least five repetitions of four typical ACL physiotherapy exercises (i.e., one leg deadlifts, hamstring curls, mini lunges and single leg squats). The one leg deadlift is a hip-hinge movement which requires the participant to lean forward with the hips shifting the weight onto one leg while the other leg extends straight behind and is lifted until the body forms a T shape. The hamstring curl is an exercise which involves bending the knee and moving the heel toward the glute while the rest of the body stays still. Mini lunges require participants to take a step forward, lower the body towards the floor by bending the knee and hip of front leg by 30 degrees, and return to the standing position. Single leg squats, instead, start by standing on one foot with the other leg lifted out and require participants to lower into a squat position and push to stand back up.

Gaps in the trajectories of the markers were filled manually with cubic spline interpolations and the time-series of the IMUs were up-sampled to match the rate of the camera system. Knee flexion was calculated from the trajectories of the thigh, shank and ankle markers, whereas the quaternions calculated from the inertial sensors in the bespoke devices (Section VII.A) were also used to approximate the same angles. Kinematics from the wearable system and the motion capture cameras were synchronized automatically in post-processing using an autocorrelation function in MATLAB, and trials were automatically cropped from the beginning to the end of the performed repetitions. Measurements from the optoelectronic and wearable systems were then compared by means of the average root mean square error (RMSE), Pearson's coefficient and the error in the range of motion (i.e., maximum flexion minus the maximum extension knee angles) were obtained for all the executed repetitions of each exercise.

TABLE 1. RMSE, pearson's coefficients and errors in the RoM of the knee flexion measurements (Optitrack vs SKYRE) for four different exercises.

	One Leg Deadlift	Single Leg Squat	Mini Lunges	Hamstring Curl	Total
RMSE ± std (°)	7.4 ±4.7	6.0 ± 3.2	7.3 ± 4.0	8.5 ± 3.0	7.4 ± 3.6
RoM error ± std (°)	10.1 ± 7.2	9.5 ± 7.0	9.9 ± 9.5	8.7 ± 10.6	9.5 ± 8.3
Pearson' r ± std	0.93 ± 0.11	0.99 ± 0.01	0.98 ± 0.03	0.99 ± 0.01	0.97 ± 0.05

Graphical representation of the curves for all four exercises (Figure 8) and the comparison measures (Table 1) indicate good accuracy in the calculation of the knee flexion/extension angles with the developed system. RMSE was between 6.0° and 8.5°, with an average of 7.4°. Pearson's r was excellent (higher than 0.93, with an average equal to 0.97) for all four exercises showing good agreement. The average error in the calculation of the total RoM was equal to 9.5° for all exercises; inspection of the flexion/extension curves indicates that the error in the total RoM measurements most likely originates from the calculation of the high extension angles in each exercise cycle, while the calculation of the maximum flexion angles shows excellent agreement.

C. sEMG VALIDATION

A convenience sample of 12 subjects (8 women, 4 men, mean age 28±2.6 years, mean height 169.7±7.6 cm, mean weight 66.5±7.1 kg) was recruited to participate in the study. Each subject was informed about the upcoming trial and the tasks given. All participants completed the consent form and the Physical Activity Readiness Questionnaire (PAR-Q) and had no self-reported musculoskeletal and skin injuries or disorders.

The Secondary unit on the calf was used for validation. Recorded data were transmitted to a laptop for post-processing synchronization with the BTS FreeEMG [74] recordings. For this analysis, three tests were carried out: SKYRE vs. BTS FreeEMG (Protocol 1), textile electrodes vs. pre-gelled electrodes (Protocol 2), and performance of textile electrodes after repeated washing (Protocol 3).

1) PROTOCOL 1

Gastrocnemius lateralis (GL) muscle activity was used to evaluate sEMG validity. Sensors (BTS probes and the system sleeve) were placed on the right and left calves (GL), according to SENIAM and BTS manufacturer guidelines. All sensors were placed on clean and dry skin, in case of significant amount of body hair (2 participants) small skin patches under adhesive electrodes were shaved. No additional preparation for textile electrodes was conducted.

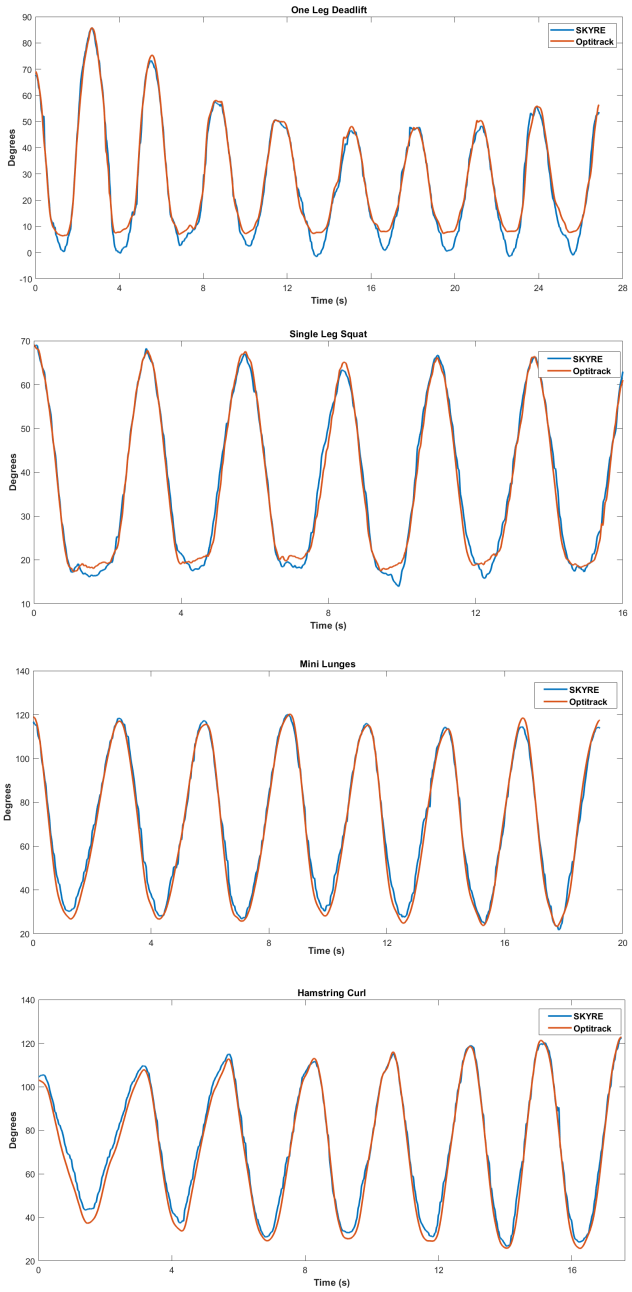

FIGURE 8. Knee flexion angles as obtained by the two systems for all four exercises.

After placing, a 5-minute delay in the recordings ensured the optimal performance of the textile electrodes.

Maximal voluntary isometric contraction (MVIC) was used as the reference sEMG value to normalize acquired data. Ankle plantar flexion (e.g., the act of extending the ankle so that the foot points down and away from the leg and then back up) was performed thrice with 2 minutes rest periods in between to measure maximum sEMG values.

After 1 minute of rest, participants were asked to stand up, relax and then raise on their tiptoes with feet pointing forward, hold this position for 2-3 seconds, then relax and stay upright for about 10 seconds. If necessary, participants

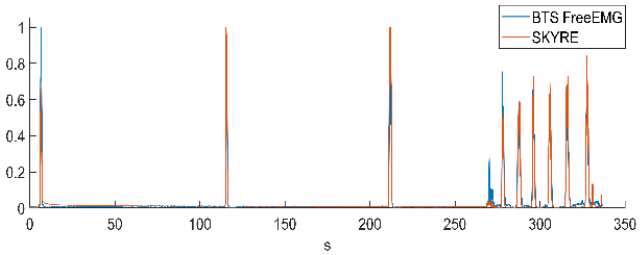

FIGURE 9. Synchronized BTS FreeEMG (blue curve) and the developed system (orange curve) sEMG for left and right legs.

were allowed to place hands on a high table to support themselves. The exercise was performed 5 times. Participants were verbally encouraged to perform movements with symmetrical load and timing for both legs.

2) PROTOCOL 2

BTS probe was removed and the developed system was connected via standard EMG cables using adhesive pre-gelled electrodes (Covidien Kendall Disposable Surface EMG/ECG/EKG Electrodes, 24mm) at exactly the same place. Participants then were asked to repeat standing on tip-toe exercise described previously. All sensors were then removed and procedure was repeated with the opposite leg after a minimum of 5 minutes rest.

3) PROTOCOL 3

The sleeve with attached electrodes was manually washed in warm water 36°C (3°C) using mild detergent (liquid detergent for delicate fabrics). Ten ml of detergent were diluted in 3 liters of water as recommended by the manufacturer. The sleeve was then gently washed for about 5 min, thoroughly rinsed and dried naturally. Previously described exercise (rising on tiptoes, 15 repetitions) was performed by 1 participant using repeatedly washed textile electrodes. Recordings were taken before washing, and after 3, and 10 washing cycles.

4) ANALYSIS

MATLAB software was used to process all gathered data. The values of the average rectified EMG data (ARV) of sEMG activity were considered. To obtain ARV, BTS records were rectified and averaged using a moving average by sliding a 200 ms window as recommended for static movements [75]. Recorded data from both systems were normalized against MVIC in the current recording (rescaled into range between 0 and 1). Records were aligned using the maximums of the ARV envelopes as points of synchronization (Figure 9). Then part of the record containing exercise repetition was manually cropped. These records were then compared. Same records went through additional post-processing, which included rescaling into 0-1 values against maximum contraction within the 5 repetitions and filtering (low-pass 4^{th} order Butterworth with cut-off frequency at 4 Hz [76]).

Pearson's coefficients of correlation were then calculated for all original and additionally processed records. Signals from different types of electrodes were analyzed with and without additional processing as well. Same procedures were applied (Figures 10). Due to impossibility of placing

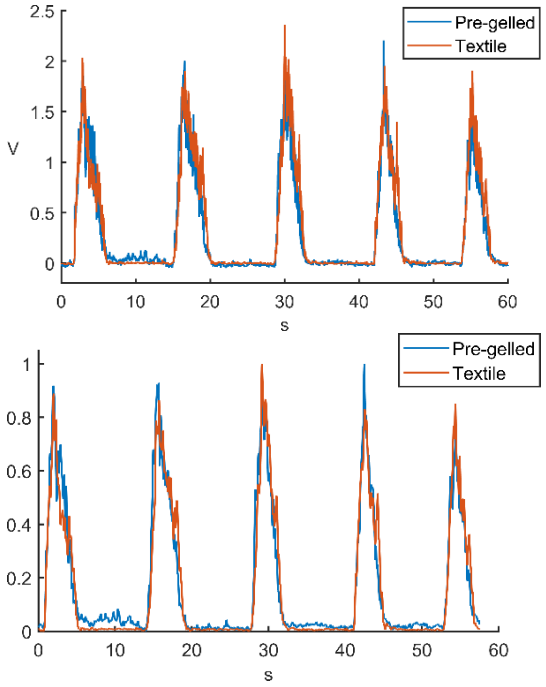

FIGURE 10. EMG for textile and adhesive pre-gelled electrodes, developed system envelope (top) and filtered envelope (bottom).

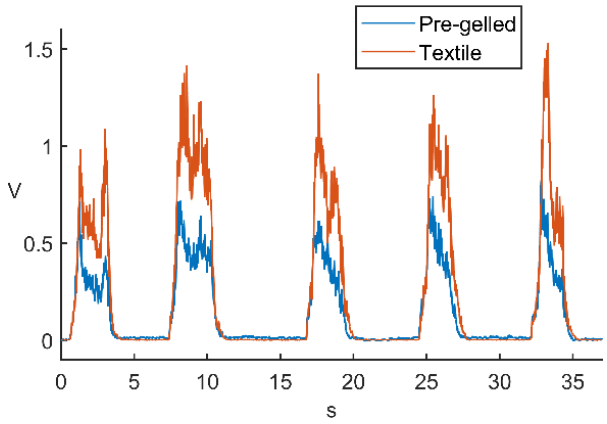

FIGURE 11. Time difference between legs movements in repetition number 3 and 4.

electrodes simultaneously on the same muscle, recordings from right and left legs were compared. Even though the performed exercise was chosen as it allows participants to perform the movement symmetrically and all participants were encouraged to stand on tiptoes simultaneously and distribute weight equally, some difference between muscles activities naturally occur, e.g., Figure 11 shows noticeable difference in the timing of the 3rd and 4th repetitions for right and left leg.

Despite this, the results obtained during the experiments show that the ARV obtained via SKYRE compares well with a gold-standard. High R values showed a strong correlation between measurements for every participant for Protocol 1 and 2. Table 2 shows values of R for all the 12 participants for signals normalized against MVIC, cropped to contain only the exercise part for left and right leg and values of R for additionally processed records (Filt.), as previously described. Table 3 shows values of R for all 12 participants for the unaltered envelope for left and right leg (Env.) and values of R for additionally processed records (Filt.).

Moreover, the textile electrodes retained their performance throughout the washing cycles (Figure 12). No significant decrease in signal amplitude was noticed. Sewn connections with conductive wires remained intact; however slight fraying of the conductive fabric edges was observed for one electrode, indicating minor inconsistency in manually performed gluing procedure that however did not affect the overall performance. This defect happened either due to inconsistency in manually performed electrodes assembly or quality of the glue used. For the manufacturing process, the manual conductive fabric attachment should be replaced by sewing the conductive fabric to the base using conductive thread or factory gluing with industrial quality glues.

D. EMS EVALUATION

For muscle electrostimulation different types of waveforms are used in literature according to the application, among which: interferential, premodulated, Russian, biphasic, etc. Each waveform is characterized by several adjustable parameters (amplitude, frequency, duty cycle/cycle time, phase duration, electrode placement). Details on the wave's characteristics and the impact that each parameter has on the patients' response are available in [77].

In SKYRE, the electrostimulation of the muscles is generated by the Primary unit through a contact connector. The board is equipped with a STM32F4 microcontroller containing a Digital to Analogue (DAC) converter. The microcontroller is programmed to generate on the two pins of the DAC a desired waveform in the range 0-3.3 Volts. The generation of the waves on the pins is Single Ended. These two pins are connected to a boost that amplifies the voltage in ''Differential'' and it is able to generate waves up to 300 Volts peak-to-peak. Once the frequency is fixed, the amplification of the boost is also set, and the wave's amplitude is varied based on the phase of the two signals outgoing from the DAC (e.g., constructive interference). An example of the implementation of the Russian waveform is discussed below. A 2.5 kHz sine wave is created and released at bursts. This is achieved via two time counters, one associated to the sine wave and the second one set to have an interrupt event every 10 milliseconds. Figure 13 shows an example of a Russian waveform realized with SKYRE. The Russian waveform represented has a peak-to-peak voltage around 76 Volts. An example of a realized 100 Hz premodulated waveform is instead shown in Figure 14. A video showing the adoption of the EMS technology via SKYRE is available in Supplementary Material 4.

IX. DISCUSSION AND FUTURE WORK

This work investigated the development of a novel wearable system for remote real-time objective assessment of clinically defined exercises in a rehabilitation process. The whole process, from market landscape to users' requirements,

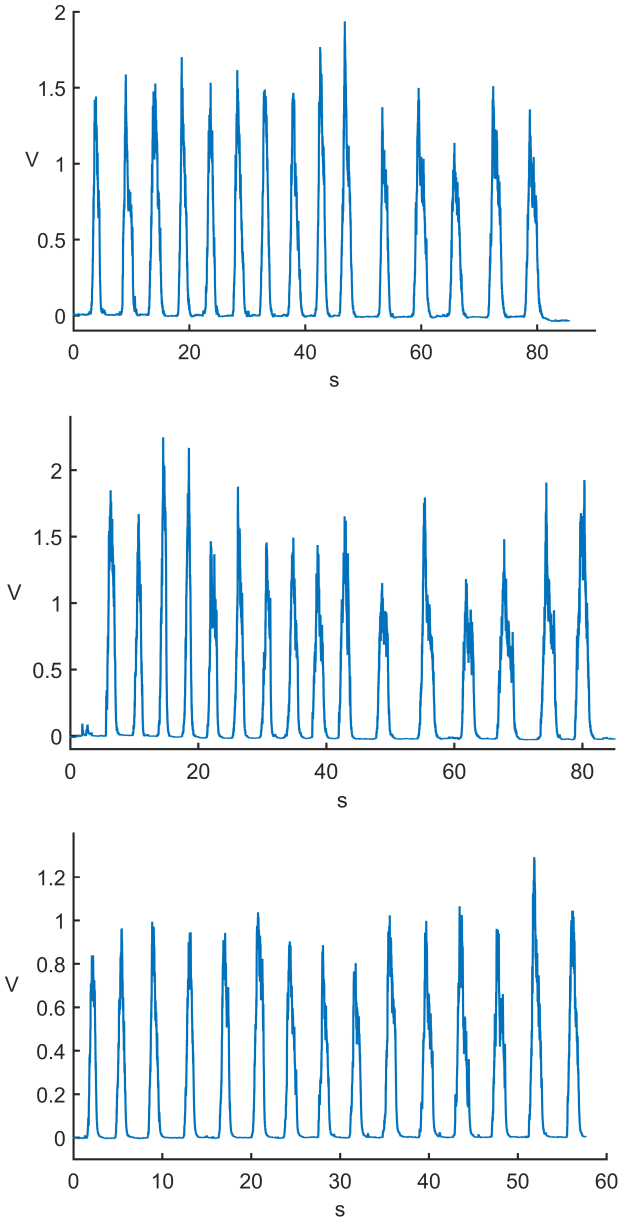

FIGURE 12. sEMG before washing (top), sEMG after 3 washing cycles (centre), sEMG after 10 washing cycles (bottom).

industrial design, system development, and validation has been carried out and presented here. System architecture, including both hardware and software platforms, have been thoroughly described, with particular emphasis on the hardware architecture, sensing technologies adopted (motion data, EMG measurements, and muscle electrostimulation), prototyping process, the mobile application and web portal implementation, as well as the wireless communication among all the system components. The developed system SKYRE meets the end-users' requirements defined initially and the adopted sensing technologies present results comparable to gold-standards. Moreover, the developed mobile application can provide guidance to the users through the rehabilitation sessions, thus increasing users' awareness and improving compliance.

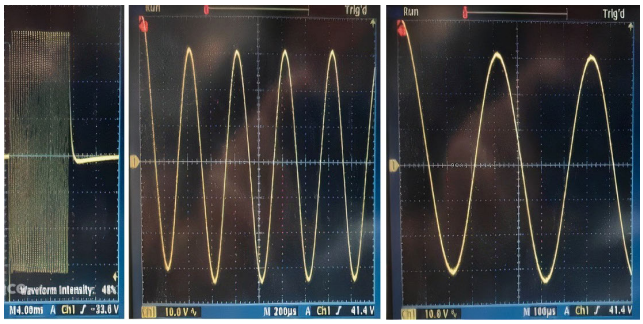

FIGURE 13. Russian waveform produced by SKYRE on the oscilloscope at three different time divisions: 4 ms time/div (left), 200 μs (centre), and 100 μs (right).

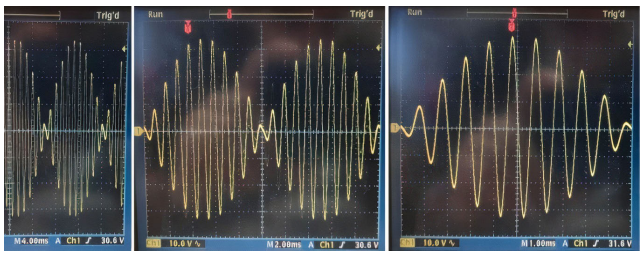

FIGURE 14. Oscilloscope images of a ∼70 V (peak-to-peak) premodulated waveform (IF-2P) produced by SKYRE at different time/divisions: 4 ms (left), 2 ms (centre), and 1 ms (right).

In summary, the developed system can enable the key advantages of remote knee rehabilitation by potentially supporting change in patient behavior, impacting patients' active participation and independent living, and reducing face-to-face sessions. By engaging all the relevant stakeholders in the industrial design stage and in the gathering of the system requirements, the technology designed in this study can impact the ways exercise therapy programs in knee rehabilitation are currently delivered, thus paving the way for tailored and personalized treatments in the future.

The sensing technologies embedded in the wearable device have been validated against several gold-standard devices showing overall good-to-excellent performance in terms of accuracy, validity, and reliability. However, despite the amount of work produced in the study, further works are still required to improve the overall system. In particular, the prototyping manufacturing process is the main influence on the system accuracy and, therefore, should be optimized in order to deliver mass-manufacturable products, which will further improve the overall performance of the system.

For SKYRE, we have utilized standard textiles which are widely available. Some of it is a 2D stretchable material, such as the one used for cycling shorts, and some of it is non-stretchable and is used to protect the electronics from mechanical damage. The assembly process for the sleeves does not require any out-of-the-ordinary technique and even the electrodes have properties that are similar to textile and, therefore, a simple sewing machine can be utilized to carry out the integration of the electrodes in to the system. However, the routing of the electrodes through the fabric to the electronics is still a complex issue, and the implemented solution

TABLE 2. Correlation coefficients: Developed system vs BTS FreeEMG.

Participant	1	2	3	4*	5	6	7	8	9	10	11	12	Mean	SD
MVIC	0.92	0.97	0.91	0.86	0.96	0.96	0.94	0.96	0.97	0.95	0.96	0.95	0.94	0.03
	0.95	0.86	0.92	*	0.96	0.94	0.96	0.94	0.93	0.93	0.94	0.84	0.92	0.04
Filt.	0.93	0.97	0.92	0.86	0.96	0.96	0.94	0.97	0.97	0.96	0.96	0.95	0.95	0.03
	0.96	0.86	0.93	*	0.97	0.94	0.96	0.95	0.93	0.93	0.94	0.84	0.93	0.04

* Record for right leg was discarded due to high amplitude of signal from textile electrodes, resulted in circuit saturation.
MVIC: Maximal voluntary isometric contraction, SD: Standard deviation

TABLE 3. Correlation coefficients: Textile vs pre-gelled adhesive electrodes.

	1	2	3	4	5	6	7	8	9	10	11	12	Mean	SD
Env.	0.97	0.88	0.97	0.91	0.88	0.96	0.94	0.95	0.74	0.95	0.95	0.94	0.92	0.06
	0.65	0.87	0.91	0.94	0.91	0.96	0.97	0.95	0.96	0.95	0.96	0.66	0.89	0.11
Filt.	0.97	0.88	0.97	0.93	0.89	0.96	0.95	0.96	0.76	0.96	0.96	0.95	0.93	0.06
	0.66	0.87	0.92	0.95	0.92	0.97	0.98	0.96	0.96	0.96	0.96	0.66	0.90	0.11

is not ideal for mass-production. Different techniques, such as conductive ink, have been investigated in preliminary research with potentially promising results [78]. Moreover, further tests are currently required for the development of a more robust, durable, and washable system.

The data analytics aspects can be further improved by including additional metrics for both patients and clinicians. The scoring approach currently adopted is a simple but yet effective; however, the current score generated by the app is based only on the overall execution of the exercise, and it may be hard to translate to real-life complex tasks (i.e., walking, taking stairs up/down) when recovering from an ACL operation. Moreover, EMG data is available to the app but it is not currently used for data analysis. Therefore, the data gathered during the performance of the rehabilitation exercises could provide more scores in which patients could match to daily activities and feeling. For example, the app could incorporate methods to score reactivity, muscle fatigability, movement variability, strength, symmetry, movement stability (i.e., as calculated in [79] for example), which can be visualized altogether via a radar chart. Moreover, the adoption of machine learning for metrics implementation will be also investigated. Indeed, the capabilities of machine learning to combine heterogeneous features, such as physiological signals and kinematics from wearables, into multi-sensor information fusion are thoroughly discussed in [80], together with a discussion on the use of deep learning to partially automate feature design efforts. Moreover, the possibility to integrate in the system additional on-body sensors (such as smart watches, smart patches, smart glasses, etc.) so as to create a wireless body area network in which trained machine learning models are distributed hierarchically to achieve an accurate holistic evaluation of the wearer's health status is also to be taken into account [81].

New exercises could be also included in the mobile application to offer even more features to patients and clinicians for a more realistic recovery plan.

The current version of the SKYRE mobile application incorporates elements for patients' engagement, such as the 3D humanoid with real-time movement, the 3D scene, live scores, positive feedback, multiple scoring charts, multimedia elements, etc. However, the mobile software structure could allow the inclusion of more games-like approaches to better improve patients' patients, making the recovery exercises more enjoyable and fun to play [36].

Finally, future works will also consider usability studies with actual end-users to further investigate the acceptability of the overall system and investigate the reliability of the implemented scores in clinical populations. Longitudinal research from pre-surgery to return-to-sport with a large number of patients with various knee conditions and their clinicians is thus intended.

X. CONCLUSION

A novel platform for the remote assessment of patients undergoing knee rehabilitation has been presented in this paper, SKYRE. The platform is based on a multi-sensor wearable garment, which can provide a real-time objective evaluation of physical exercises, and an ICT architecture, which can support clinicians in their decision-making process and provide guidance to the end-users, thus increasing their awareness and compliance.

Users' requirements, industrial design, system development, and validation have been thoroughly discussed in details, including the hardware architecture, multi-sensing technologies adopted, prototyping process, mobile application and web portal implementation, as well as wireless communication among all the system components.

The developed system SKYRE meets the end-users' requirements and the multi-sensing technologies adopted present results comparable to gold-standards. SKYRE therefore might represent a valid alternative for patients and clinicians willing to perform a remote objective assessment of the rehabilitation process following knee surgery.

APPENDIX

Appendixes A-B-C-D and supplementary materials 1-2-3-4 are available on separate files.

ACKNOWLEDGMENT

The authors would like to thank Design Partners [50] for the support provided in the development of the industrial design concept, and all the participants who voluntarily took part in the study. They would also like to thank Nektaria Dagini and Sonia Bottone for their contributions to the project. The sponsors did not have any role in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication.

REFERENCES

[1] H. M. Kremers, D. R. Larson, C. S. Crowson, W. K. Kremers, R. E. Washington, C. A. Steiner, W. A. Jiranek, and D. J. Berry, "Prevalence of total hip and knee replacement in the United States," *J. Bone Joint Surg. Amer.*, vol. 97, no. 17, pp. 1386–1397, 2015.

[2] NHS. *Knee Replacement*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.nhs.uk/conditions/knee-replacement/

[3] T. Khan, A. Alvand, D. Prieto-Alhambra, D. J. Culliford, A. Judge, W. F. Jackson, B. E. Scammell, N. K. Arden, and A. J. Price, "ACL and meniscal injuries increase the risk of primary total knee replacement for osteoarthritis: A matched case–control study using the clinical practice research datalink (CPRD)," *Brit. J. Sports Med.*, vol. 53, no. 15, pp. 965–968, Aug. 2019.

[4] S. G. F. Abram, A. Judge, T. Khan, D. J. Beard, and A. J. Price, "Rates of knee arthroplasty in anterior cruciate ligament reconstructed patients: A longitudinal cohort study of 111,212 procedures over 20 years," *Acta Orthopaedica*, vol. 90, no. 6, pp. 568–574, Nov. 2019.

[5] J. T. Cavanaugh and M. Powers, "ACL rehabilitation progression: Where are we now?" *Current Rev. Musculoskeletal Med.*, vol. 10, no. 3, pp. 289–296, Sep. 2017.

[6] V. Joukov, M. Karg, and D. Kulic, "Online tracking of the lower body joint angles using IMUs for gait rehabilitation," in *Proc. 36th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc.*, Aug. 2014, pp. 2310–2313.

[7] E. C. Rodriguez-Merchan, "Knee instruments and rating scales designed to measure outcomes," *J. Orthopaedics Traumatol.*, vol. 13, no. 1, pp. 1–6, Mar. 2012.

[8] X. Wang, D. J. Hunter, G. Vesentini, D. Pozzobon, and M. L. Ferreira, "Technology-assisted rehabilitation following total knee or hip replacement for people with osteoarthritis: A systematic review and meta-analysis," *BMC Musculoskeletal Disorders*, vol. 20, no. 1, pp. 1–17, Dec. 2019.

[9] K. M. Esquivel, E. Nevala, A. Alamaki, J. Condell, D. Kelly, R. Davies, D. Heaney, A. Nordstrom, M. A. Larsson, D. Nilsson, J. Barton, and S. Tedesco, "Remote rehabilitation: A solution to overloaded & scarce health care systems," *Trends Telemedicine E-Health*, vol. 1, no. 1, pp. 1–19, 2018.

[10] T. Latif-Zade, B. Tucci, D. Verbovetskaya, E. Bialkin, B. Ng, S. Heddon, and J.-P. Berteau, "Systematic review shows tele-rehabilitation might achieve comparable results to office-based rehabilitation for decreasing pain in patients with knee osteoarthritis," *Medicina*, vol. 57, no. 8, p. 764, Jul. 2021.

[11] W. Petersen, K. Karpinski, L. Backhaus, S. Bierke, and M. Häner, "A systematic review about telemedicine in orthopedics," *Arch. Orthopaedic Trauma Surg.*, vol. 141, no. 10, pp. 1731–1739, Oct. 2021.

[12] S. Bahadori, T. Immins, and T. W. Wainwright, "A review of wearable motion tracking systems used in rehabilitation following hip and knee replacement," *J. Rehabil. Assistive Technol. Eng.*, vol. 5, pp. 1–8, Apr. 2018.

[13] S. R. Small, G. S. Bullock, S. Khalid, K. Barker, M. Trivella, and A. J. Price, "Current clinical utilisation of wearable motion sensors for the assessment of outcome following knee arthroplasty: A scoping review," *BMJ Open*, vol. 9, no. 12, Dec. 2019, Art. no. e033832.

[14] O. A. Malik, S. M. N. A. Senanayake, and D. Zaheer, "An intelligent recovery progress evaluation system for ACL reconstructed subjects using integrated 3-D kinematics and EMG features," *IEEE J. Biomed. Health Informat.*, vol. 19, no. 2, pp. 453–463, Mar. 2015.

[15] T. E. Flaxman, T. Alkjær, K. B. Smale, E. B. Simonsen, M. R. Krogsgaard, and D. L. Benoit, "Differences in EMG–moment relationships between ACL-injured and uninjured adults during a weight-bearing multidirectional force control task," *J. Orthopaedic Res.*, vol. 37, no. 1, pp. 113–123, Jan. 2019.

[16] A. Palumbo, P. Vizza, B. Calabrese, and N. Ielpo, "Biopotential signal monitoring systems in rehabilitation: A review," *Sensors*, vol. 21, no. 21, p. 7172, Oct. 2021.

[17] Y. Bouteraa, I. B. Abdallah, K. Alnowaiser, and A. Ibrahim, "Smart solution for pain detection in remote rehabilitation," *Alexandria Eng. J.*, vol. 60, no. 4, pp. 3485–3500, Aug. 2021.

[18] Q. Meng, J. Zhang, and X. Yang, "Virtual rehabilitation training system based on surface EMG feature extraction and analysis," *J. Med. Syst.*, vol. 43, no. 3, Mar. 2019.

[19] O. E. Ogul, D. K. Coskunsu, S. Akcay, K. Akyol, L. Hanoglu, and N. Ozturk, "The effect of electromyography (EMG)-driven robotic treatment on the recovery of the hand nine years after stroke," *J. Hand Therapy*, vol. S0894-1130, no. 21, pp. 00069-1–00069-7, Apr. 2021.

[20] Y. Nishikawa, K. Watanabe, S. Kawade, T. Takahashi, H. Kimura, H. Maruyama, and A. Hyngstrom, "The effect of a portable electrical muscle stimulation device at home on muscle strength and activation patterns in locomotive syndrome patients: A randomized control trial," *J. Electromyogr. Kinesiol.*, vol. 45, pp. 46–52, Apr. 2019.

[21] K. Monte-Silva, D. Piscitelli, N. Norouzi-Gheidari, M. A. P. Batalla, P. Archambault, and M. F. Levin, "Electromyogram-related neuromuscular electrical stimulation for restoring wrist and hand movement in poststroke hemiplegia: A systematic review and meta-analysis," *Neurorehabilitation Neural Repair*, vol. 33, no. 2, pp. 96–111, Feb. 2019.

[22] J. Rahman, Q. Tang, M. Monda, J. Miles, and I. McCarthy, "Gait assessment as a functional outcome measure in total knee arthroplasty: A cross-sectional study," *BMC Musculoskeletal Disorders*, vol. 16, no. 1, Dec. 2015.

[23] R. Ali, L. Atallah, B. Lo, and G. Z. Yang, "Detection and analysis of transitional activity in manifold space," *IEEE Trans. Inf. Technol. Biomed.*, vol. 16, no. 1, pp. 28–119, Aug. 2012.

[24] C. L. Christiansen, M. J. Bade, R. J. Paxton, and J. E. Stevens-Lapsley, "Measuring movement symmetry using tibial-mounted accelerometers for people recovering from total knee arthroplasty," *Clin. Biomechanics*, vol. 30, no. 7, pp. 732–737, Aug. 2015.

[25] R. M. Kwasnicki, R. Ali, S. J. Jordan, L. Atallah, J. J. H. Leong, G. G. Jones, J. Cobb, G. Z. Yang, and A. Darzi, "A wearable mobility assessment device for total knee replacement: A longitudinal feasibility study," *Int. J. Surg.*, vol. 18, pp. 14–20, Jun. 2015.

[26] H.-H. Zhang, S.-H. Yan, C. Fang, X.-Y. Guo, and K. Zhang, "Clinical evaluation and gait characteristics before and after total knee arthroplasty based on a portable gait analyzer," *Orthopaedic Surg.*, vol. 8, no. 3, pp. 360–366, Aug. 2016.

[27] R. M. Chapman, W. E. Moschetti, and D. W. Van Citters, "Stance and swing phase knee flexion recover at different rates following total knee arthroplasty: An inertial measurement unit study," *J. Biomech.*, vol. 84, pp. 129–137, Feb. 2019.

[28] S. A. A. N. Bolink, B. Grimm, and I. C. Heyligers, "Patient-reported outcome measures versus inertial performance-based outcome measures: A prospective study in patients undergoing primary total knee arthroplasty," *Knee*, vol. 22, no. 6, pp. 618–623, Dec. 2015.

[29] C.-Y. Chiang, K.-H. Chen, K.-C. Liu, S. Hsu, and C.-T. Chan, "Data collection and analysis using wearable sensors for monitoring knee range of motion after total knee arthroplasty," *Sensors*, vol. 17, no. 2, p. 418, Feb. 2017.

[30] Y. Hiyama, T. Asai, O. Wada, H. Maruno, S. Nitta, K. Mizuno, Y. Iwasaki, and S. Okada, "Gait variability before surgery and at discharge in patients who undergo total knee arthroplasty: A cohort study," *PLoS ONE*, vol. 10, no. 1, Jan. 2015, Art. no. e0117683.

[31] F. Kluge, J. Hannink, C. Pasluosta, J. Klucken, H. Gaßner, K. Gelse, B. M. Eskofier, and S. Krinner, "Pre-operative sensor-based gait parameters predict functional outcome after total knee arthroplasty," *Gait Posture*, vol. 66, pp. 194–200, Oct. 2018.

[32] P. N. Ramkumar, H. S. Haeberle, D. Ramanathan, W. A. Cantrell, S. M. Navarro, M. A. Mont, M. Bloomfield, and B. M. Patterson, "Remote patient monitoring using mobile health for total knee arthroplasty: Validation of a wearable and machine learning–based surveillance platform," *J. Arthroplasty*, vol. 34, no. 10, pp. 2253–2259, Oct. 2019.

[33] O. M. Giggins, K. T. Sweeney, and B. Caulfield, "Rehabilitation exercise assessment using inertial sensors: A cross-sectional analytical study," *J. Neuroeng. Rehabil.*, vol. 11, no. 1, p. 158, 2014.

[34] R. Houmanfar, M. Karg, and D. Kulic, "Movement analysis of rehabilitation exercises: Distance metrics for measuring patient progress," *IEEE Syst. J.*, vol. 10, no. 3, pp. 1014–1025, Sep. 2016.

[35] R. Argent, P. Slevin, A. Bevilacqua, M. Neligan, A. Daly, and B. Caulfield, "Wearable sensor-based exercise biofeedback for orthopaedic rehabilitation: A mixed methods user evaluation of a prototype system," *Sensors*, vol. 19, no. 2, p. 432, Jan. 2019.

[36] G. Kontadakis, D. Chasiouras, D. Proimaki, M. Halkiadakis, M. Fyntikaki, and K. Mania, "Gamified platform for rehabilitation after total knee replacement surgery employing low cost and portable inertial measurement sensor node," *Multimedia Tools Appl.*, vol. 79, nos. 5–6, pp. 3161–3188, Feb. 2020.

[37] T. Boucher, S. Wang, E. Trudelle-Jackson, and S. Olson, "Effectiveness of surface electromyographic biofeedback-triggered neuromuscular electrical stimulation on knee rehabilitation," *North Amer. J. Sports Phys. Therapy*, vol. 4, no. 3, pp. 100–109, 2009.

[38] D. O'Connor, L. Brennan, and B. Caulfield, "The use of neuromuscular electrical stimulation (NMES) for managing the complications of ageing related to reduced exercise participation," *Maturitas*, vol. 113, pp. 13–20, Jul. 2018.

[39] B. Oubre, J.-F. Daneault, K. Boyer, J. H. Kim, M. Jasim, P. Bonato, and S. I. Lee, "A simple low-cost wearable sensor for long-term ambulatory monitoring of knee joint kinematics," *IEEE Trans. Biomed. Eng.*, vol. 67, no. 12, pp. 3483–3490, Dec. 2020.

[40] L. S. Vargas-Valencia, F. B. A. Schneider, A. G. Leal-Junior, P. Caicedo-Rodriguez, W. A. Sierra-Arevalo, L. E. Rodriguez-Cheu, T. Bastos-Filho, and A. Frizera-Neto, "Sleeve for knee angle monitoring: An IMU-POF sensor fusion system," *IEEE J. Biomed. Health Informat.*, vol. 25, no. 2, pp. 465–474, Feb. 2021.

[41] O. T. Inan, D. C. Whittingslow, C. N. Teague, S. Hersek, M. B. Pouyan, M. Millard-Stafford, G. F. Kogler, and M. N. Sawka, "Wearable knee health system employing novel physiological biomarkers," *J. Appl. Physiol.*, vol. 124, no. 3, pp. 537–547, Mar. 2018.

[42] L. Khokhlova, D.-S. Komaris, S. Tedesco, and B. O'Flynn, "Assessment of hip and knee joints and implants using acoustic emission monitoring: A scoping review," *IEEE Sensors J.*, vol. 21, no. 13, pp. 14379–14388, Jul. 2021.

[43] BCC Research Staff, *Wearable Medical Devices: Technologies and Global Markets*. BCC Publishing, Mar. 2019.

[44] MIRA Rehab. *Play Your Way to Recovery*. Accessed: Sep. 10, 2022. [Online]. Available: http://www.mirarehab.com/

[45] *Reflexion Health*. Accessed: Sep. 10, 2022. [Online]. Available: http://reflexionhealth.com/

[46] Jintronix. *Interactive Technology for Rehabilitation and Senior Care*. Accessed: Sep. 10, 2022. [Online]. Available: https://jintronix.com/

[47] Corehab. *We Measure the Movement*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.corehab.it/en/

[48] SWORD Health. *Freeing the World From Pain*. Accessed: Sep. 10, 2022. [Online]. Available: https://swordhealth.com/

[49] Hinge Health. *Personalized Care for Back and Joint Pain*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.hingehealth.com/

[50] Claris Reflex. *The Time for Remote Rehabilitation is Now*. Accessed: Sep. 10, 2022. [Online]. Available: https://clarisreflex.com/

[51] Breg Flex. *Breg Launches Sensor-Plus-App Wearable Health Solution for Improved At-Home Recovery*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.breg.com/breg-launches-sensor-plus-app-wearable-health-solution-for-improved-at-home-recovery/

[52] TracPatch. *Restore. Revive. Go*. Accessed: Sep. 10, 2022. [Online]. Available: https://tracpatch.com/

[53] BPMpathway. *The Proven Dimension in Remote Patient Assessment*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.bpmpathway.com/

[54] OPED. *Orthelligent Knee Rehab*. Accessed: Sep. 10, 2022. [Online]. Available: https://opedmedical.com/product/orthelligent-knee/

[55] I. Spasić, K. Button, A. Divoli, S. Gupta, T. Pataky, D. Pizzocaro, A. Preece, R. van Deursen, and C. Wilson, "TRAK app suite: A web-based intervention for delivering standard care for the rehabilitation of knee conditions," *JMIR Res. Protocols*, vol. 4, no. 4, p. e122, Oct. 2015.

[56] Design Partners. *Reinventing the Patient-Physio Relationship*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.designpartners.com/projects/reinventing-patient-physio-relationships/

[57] InvenSense. *MPU-9250*. Accessed: Sep. 10, 2022. [Online]. Available: https://invensense.tdk.com/products/motion-tracking/9-axis/mpu-9250/

[58] STMicroelectronics. *Life.augmented*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.st.com/content/st_com/en.html

[59] Texas Instruments. Accessed: Sep. 10, 2022. [Online]. Available: https://www.ti.com/

[60] S. Tedesco, M. Belcastro, O. M. Torre, P. Torchia, D. Alfieri, L. Khokhlova, and B. O'Flynn, "A multi-sensors wearable system for remote assessment of physiotherapy exercises during ACL rehabilitation," in *Proc. 26th IEEE Int. Conf. Electron., Circuits Syst. (ICECS)*, Nov. 2019, pp. 27–29.

[61] Shieldex. *Metallised Textiles for Challenges that Matter*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.shieldex.de/

[62] A. Ankhili, X. Tao, C. Cochrane, V. Koncar, D. Coulon, and J.-M. Tarlet, "Comparative study on conductive knitted fabric electrodes for long-term electrocardiography monitoring: Silver-plated and PEDOT: PSS coated fabrics," *Sensors*, vol. 18, no. 11, p. 3890, Nov. 2018.

[63] A. P. Catarino, H. Carvalho, A. M. Rocha, G. Montagna, and M. J. Dias, "Biosignal monitoring implemented in a swimsuit for athlete performance evaluation," in *Proc. AUTEX*, 2011, pp. 807–813.

[64] L. Beckmann, C. Neuhaus, G. Medrano, N. Jungbecker, M. Walter, T. Gries, and S. Leonhardt, "Characterization of textile electrodes and conductors using standardized measurement setups," *Physiol. Meas.*, vol. 31, no. 2, pp. 233–247, Feb. 2010.

[65] C. Pylatiuk, M. Müller-Riederer, A. Kargov, S. Schulz, O. Schill, M. Reischl, and G. Bretthauer, "Comparison of surface EMG monitoring electrodes for long-term use in rehabilitation device control," in *Proc. IEEE Int. Conf. Rehabil. Robot.*, Jun. 2009, pp. 300–304.

[66] A. Soroudi, N. Hernández, J. Wipenmyr, and V. Nierstrasz, "Surface modification of textile electrodes to improve electrocardiography signals in wearable smart garment," *J. Mater. Sci. Mater. Electron.*, vol. 30, pp. 1–10, Aug. 2019.

[67] L. Khokhlova, M. Belcastro, P. Torchia, B. O'Flynn, and S. Tedesco, "Wearable textile-based device for human lower-limbs kinematics and muscle activity sensing," in *Wearables in Healthcare* (Lecture Notes of the Institute for Computer Sciences, Social Informatics and Telecommunications Engineering), vol. 376. Cham, Switzerland: Springer, 2021, pp. 70–81.

[68] S. O. H. Madgwick, A. J. L. Harrison, and R. Vaidyanathan, "Estimation of IMU and MARG orientation using a gradient descent algorithm," in *Proc. IEEE Int. Conf. Rehabil. Robot.*, Zurich, Switzerland, Jun. 2011, pp. 1–7.

[69] S. van Grinsven, R. van Cingel, C. J. M. Holla, and C. J. M. van Loon, "Evidence-based rehabilitation following anterior cruciate ligament reconstruction," *Knee Surgery Sports Traumatol. Arthroscopy*, vol. 18, no. 8, pp. 1128–1144, 2010.

[70] X. Yu and S. Xiong, "A dynamic time warping based algorithm to evaluate Kinect-enabled home-based physical rehabilitation exercises for older people," *Sensors*, vol. 19, no. 13, p. 2882, Jun. 2019.

[71] R. H. Osgouei, D. Soulsbv, and F. Bello, "An objective evaluation method for rehabilitation exergames," in *Proc. IEEE Games, Entertainment, Media Conf. (GEM)*, Aug. 2018, pp. 28–34.

[72] M. H. Schwartz and A. Rozumalski, "The gait deviation index: A new comprehensive index of gait pathology," *Gait Posture*, vol. 28, no. 3, pp. 351–357, Oct. 2008.

[73] Ramer Douglas Peucker. *Javascript Implementation of the Ramer Douglas Peucker Algorithm*. Accessed: Sep. 10, 2022. [Online]. Available: https://karthaus.nl/rdp/

[74] BTS Bioengineering FreeEMG. *Electromyography Device With Wireless Probes for the Dynamic Analysis of Muscle Activity*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.btsbioengineering.com/products/freeemg/

[75] F. D. Farfán, J. C. Politti, and C. J. Felice, "Evaluation of EMG processing techniques using information theory," *Biomed. Eng. OnLine*, vol. 9, no. 1, p. 72, Dec. 2010.

[76] P. Konrad, "The ABC of EMG—A practical introduction to kinesiological electromyography," Version 1.4, Noraxon, Scottsdale, AZ, USA, Tech. Rep., Mar. 2006.

[77] ProHealthcareProducts.com. *Electrotherapy Indications and Contraindications*. Accessed: Sep. 10, 2022. [Online]. Available: https://www.prohealthcareproducts.com/blog/electrotherapy-indications-and-contraindications/

[78] A. Federico, M. Belcastro, P. Torchia, S. Tedesco, and B. O'Flynn, "Investigation on the use of the PE873 conductive ink for surface EMG measurements," in *Proc. IARIA*, 2020, pp. 47–51.

[79] D.-S. Komaris, G. Tarfali, B. O'Flynn, and S. Tedesco, "Unsupervised IMU-based evaluation of at-home exercise programmes: A feasibility study," *BMC Sports Sci., Med. Rehabil.*, vol. 14, no. 1, pp. 1–12, Dec. 2022.

[80] S. Qiu, H. Zhao, N. Jiang, Z. Wang, L. Liu, Y. An, H. Zhao, X. Miao, R. Liu, and G. Fortino, "Multi-sensor information fusion based on machine learning for real applications in human activity recognition: State-of-the-art and research challenges," *Inf. Fusion*, vol. 80, pp. 241–265, Apr. 2022.
[81] M. Seiffert, F. Holstein, R. Schlosser, and J. Schiller, "Next generation cooperative wearables: Generalized activity assessment computed fully distributed within a wireless body area network," *IEEE Access*, vol. 5, pp. 16793–16807, 2017.

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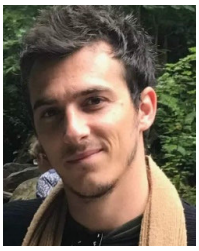

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