Preliminary design of a wearable system to increase adherence to rehabilitation programmes in acute Cruciate Ligament (CL) rupture

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ABSTRACT

The effectiveness of rehabilitation in acute cruciate ligament (CL) rupture is dependent upon patient adherence to Home Exercise Programmes (HEPs) and self-efficacy. This paper presents the research, preliminary design stages and an early evaluation of a digital wearable system for monitoring, tracking, guiding and motivating users during HEP. The aim of the prototype is to support patients' rehabilitation programme by reducing the risk of re-injury during the process and motivate them to adhere to their HEPs by providing constructive feedback, encouraging understanding and thus promoting self-efficacy. The digital infrastructure is composed of three main parts, a physical product of two smart bracelets for sensing data from the patient's knee, a smartphone application for the user to interact with and a web-based service for collecting, storing, analysing and sharing data.

CCS CONCEPTS

• Human-centered computing~Interaction design • Human-centered computing~Interface design prototyping • Social and professional topics~Medical technologies • Hardware~Sensors and actuators

KEYWORDS

wearable health technologies, mHealth, cruciate ligament rupture, knee rehabilitation, monitoring, self-efficacy

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1 Introduction

The importance of bio-medical engineering and wearable solutions for healthcare is growing during the last decades thanks to the improvement and the availability of many devices and technological solutions, as well as their cost reduction. As a consequence, the interest in applying and combining those technologies to the monitoring and treatment of several kinds of diseases has increased [1]. A tear of Cruciate Ligament (CL) is a common knee injury that occurs mostly among athletes. Rehabilitation after an CL injury can last as long as a year and often includes physical therapy, strength exercises and frequent visits to physiotherapists and doctors.

The broader scope of digital health and health wearables is to provide patients with technologies (hardware devices, software tools/systems and online services) to better monitor, track and eventually manage their health and wellness related activities [2]. Wearable health monitoring systems integrated into telemedicine systems are novel information technologies that support early detection of abnormal conditions and potentially prevent serious consequences of non-adherence with physiotherapy treatment. Many patients can benefit from continuous monitoring as a part of a diagnostic procedure, optimal maintenance of a chronic condition or during supervised recovery from an acute event or surgical procedure. Wearable technologies and biofeedback systems appear to be a valid alternative, as they reduce the extensive time to setup a patient before each session and require limited time involvement of physicians and therapists [3]. Researchers have focused on three main areas of work to develop tools of clinical interest: the design and implementation of *sensors* that are minimally obtrusive and reliably record movement or physiological signals, the development of *systems* that unobtrusively gather data from multiple wearable sensors and deliver this information to clinicians in the way that is most appropriate for each treatment, and the design and implementation of *algorithms* to extract clinically relevant information from data recorded using wearable technology.

In this project attention is given on people who experience CL rupture and are at the stage of recovery. The effectiveness of exercise programs for CL injuries is dependent upon patient *adherence* to *HEPs* and the development *self-efficacy*. *Adherence* can be defined as an active, voluntary, collaborative involvement of the patient in a mutually acceptable course of behaviour to produce a desired therapeutic result [4]. *Self-efficacy*, defined as one's belief in one's ability to perform a particular task, may be addressed by clinicians working with patients with musculoskeletal conditions to improve adherence to exercise programs [5]. The use of exercise programs, both in the clinic and at home, is the standard of care for musculoskeletal disorders, with patient adherence being necessary to increase and sustain self-efficacy. *Home exercise programs* (HEPs) reduce the number of visits needed in a clinic each week, saving resources and effort for both the patients and insurance companies. Also, researchers have identified personal factors that contribute to lack of adherence to HEPs such as, helplessness, depression, anxiety, increased pain with exercise, the patient’s perception of barriers that they encounter, low self-motivation and low self-efficacy [6].

In the following paragraphs, we analyse CL, the characteristics of a rehabilitation program, the need for improving users HEPs adherence through self-efficacy and processes of monitoring, tracking and guiding with wearable health technologies. We provide an overview of related projects and present our research, preliminary design stages and an early evaluation of a digital wearable product for monitoring the rehabilitation program. Finally, we also outline some insights for future work.

2 Cruciate Ligament (CL) and Injuries

CLs are the key knee stabilisers, necessary for both static and dynamic stability. CLs consist of the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL), and their purpose is to stabilise the knee especially during rotation, sidestepping and pivoting movements [7]. Knee injuries to young athletes make up 60% of sports surgeries and according to some recent studies, 50% of these include injuries to the ACL [8]. Ruptures of the CLs usually result either from the rapid deceleration of the lower limbs associated with the quadriceps or in a sudden change of direction or landing with slight knee overexposure. There are three mechanisms of the anterior cruciate ligament injury: direct contact, indirect contact and noncontact [9].

The patient who has a rupture of the CL usually has pain, premature swelling, knee fluid, limb in knee movement and difficulty in lifting weight [10]. Proper diagnosis is essential for a well-designed recovery program. The Dutch Orthopaedic Association's clinical guidelines for the diagnosis of rupture of the CL are the Lachman test, the Anterior Drawer Test, the Pivot Shift Test, and the MRI [7].

Researchers at the University of Delaware have identified two categories of injured who appear to react differently to the CL injury [11]. The first category, which is the largest, is characterised as "noncopers" and the second as "copers". Noncopers cannot return to a high-level sporting activity without having surgery to repair their CL, while copers can return to the activities they did before their injury after completing a well-designed rehabilitation program without being subjected to surgery.

2.1 CL Rehabilitation Protocol & Benefits of Monitoring

Structured rehabilitation for rupture of the anterior cruciate ligament is similar for injured patients treated with surgery or with conservative treatment. In general, the recovery program includes cold-therapy (ice), gravity-induced or continuous passive motion (continuous machine motion), brace, electrical neuromuscular stimulation and exercises (e.g. isometric, isotonic, isokinetic) with the aim of empowering, balancing, proprioception regarding the mitigation of the inflammatory reaction [9]. The above objectives can be achieved through a well-designed rehabilitation program divided into three phases, the acute phase, the recovery phase and the functional phase [11]. Recent studies show that 70% of the people are quitting physiotherapy sessions when the acute pain disappears and they regain confidence about their mobility. The reasons are multiple, and we mention a few of them: cost of treatment, the feeling that they recovered, no more time to dedicate for recovery and the loss of motivation. The worst part is that half of them are able to see the injury reappear in the course of 2-3 years [12].

The physical therapist (PT) is responsible for designing the recovery program, on the other hand the patient is responsible for maintaining and completing it since most of the process will take place at the patient's home. We see, therefore, that there is a need for regular monitoring, data recording and guidance during rehabilitation program. Wearable devices have begun to focus on digital health and now are able for monitor accurately the recovery process according to each patient's treatment plan. Wearable sensors can provide a safer environment for successfully completing the rehabilitation protocol. The (PT) receives the captured data in order to analyse it and reconsider the effectiveness of the recommended programme.

3 Related Work

Wearable Health Devices (WHDs) are emerging technologies that enable continuous ambulatory monitoring of human vital signs during daily life (at work, home, during sport activities, etc.) or in a clinical environment, with the advantage of minimising discomfort and interference with normal human activities [13]. The use of WHDs allows the ambulatory acquisition of vital signs and health status monitoring over extended periods (days/weeks) and outside clinical environments. This functionality allows sensing and capturing of data during different daily activities, ensuring a better support in medical diagnosis and/or helping in a more appropriate and faster recovering compared to a medical intervention, medical–pharmacological treatment or surgery [14]. This process of data collection is usually complemented by companion smartphone applications and/or desktop computer software for more sophisticated data analysis and visualisation, and lately stored in the cloud [15]. These devices can be used for both medical and fitness/wellness purposes, always targeting the monitoring of the human body. Wearable sensors are used to gather physiological and motion data thus enabling patients' monitoring their current status [16]. They can be extremely useful in providing accurate and reliable information on peoples' activities and behaviours, thereby ensuring a safe and sound living environment [17]. The technological revolution in the miniaturisation of electronic devices is enabling to design more reliable and adaptable wearables, contributing for a world-wide change in the health monitoring approach.

3.1 Related Projects

There is a large number of low cost wearable devices, prototypes and smartphone applications used for monitoring, tracking and guiding in real time during knee rehabilitation as part of an in-home physical therapy program. Few of them focus on rehabilitation programmes after ACL injury. In 2007 a research group from Australia developed a unique textile-based device, the intelligent knee sleeve (IKS), which uses conducting polymer technology to provide feedback on knee flexion angle for injury prevention programs [18]. The IKS contains minimal rigid components, conforms to body shape, is lightweight, does not impede human performance, is safe to be worn during physical activity and provides immediate, individualised biofeedback. The main function of this device is to reduce the risk of a non-contact ACL injury [19]. Another monitoring device prototype, in 2013, a wearable device for visualising knee rehabilitation exercises [20]. This device focuses in the recovery process at home for patients undergoing knee rehabilitation, specifically on the knee extension exercises. To better understand the needs of patients, they explored the design of a wearable electronic device that utilises an electroluminescent (EL) display as a feedback mechanism with patients who have or are currently attending physical therapy for knee rehabilitation. KneeHapp is compression bandage that tracks patient's movements during different rehabilitation exercises and gives feedback to patients and orthopaedists about the quality of the performed exercises [21]. Developed in 2015, KneeHapp supports the entire rehabilitation of an ACL injury including the recovery of flexibility, muscle strength and coordination and is intended to be used by patients at home and unsupervised. Another category of projects aims at supporting patients in adhering to the long rehabilitation processes during their recovery by the use of motivational techniques that involve gamification and other engagement and persuasion mechanisms [22], [23]. These systems do not focus in guiding users in completing accurately their HEP, neither in supporting the development of self-efficacy, but rather focus in enjoyment and care continuity.

4 Methodology, Design and Prototyping

4.1 Methodology

The methodology used in this work is a combination of design methodologies, Lean Start-Up and Agile, which are widely used to design digital services. Initially we set the problem space by defining the users' needs. Emphasis is given to the user by following a human-centrered perspective during the initial planning process [24]. Design tools and approaches were systematically used along with innovative design solutions that focus in meeting the expectations of users. Lean Start-Up methodology is used for prototypingby creating iteratively prototypes and Proof-Of-Concepts (POC) quickly using e.g. visual cards, development kit or 3D-printers, so that the feasibility of both the concept and technology choices can be confirmed [25]. Agile was used as an approach for incremental development and testing, both done in short iterations [26].

4.2 Design and Prototyping

Design Requirements

The word wearable implies the use of the human body as a support environment for the product. The human body is active, its form is diverse and changing. Wearable design that respects these dynamics results in product wearability [27].

A design process involves a set of procedures of problem solving where various types of information are collected and synthesised to generate a consistent concept followed by a visual form. Recent studies identify wearability principles which involve hardware and software aspects of devices as well as human and contextual aspects [28], [29]. The design requirements for this study include: *Wearability* considers the physical shape of objects and their active relationship with the human form. It also includes principles such as comfort, affordance, aesthetics and ergonomics. These refer to the physical shape of the device and its functionality, user physiological and psychological characteristics. It is a key factor for the usability and effectiveness of a device and influences users' engagement and satisfaction. 'Dynamic wearability' occurs when the device is worn in action. *Contextual-awareness* refers to the scenarios in which the wearable device will be used must be clearly understood and considered during the design process. *Ease of Use* refers to straightforward, simple and intuitive interface that enhances the usability of the device and further engages users with the underlying application. *Obtrusiveness* is related to physiological sensors have various degrees of intrusiveness, where intrusion may involve using body tissue to diagnose a particular physiological state or condition. Devices should be transparent, enabling natural body movements and carefully considering anatomical characteristics and constraints of the human body. *Reliability*, refers to the level of confidence and trust that users have on the device, concerns safety, precision and effectiveness. *Responsiveness*, ensuring high responsiveness helps users to complete their tasks more efficiently and productively.

Industrial Design

Design of the industrial product is considered important for a number of reasons. The designed product complies with the design requirements and fulfills the users' needs. The actual design consists of two bracelets made of special elastic fabric (hypoallergenic) mixed with soft plastic bump for better grip that the user wears when performing the recovery exercises. The main bracelet is placed on the upper leg and in particular at the area of the quadriceps-hamstring muscles while the second part will be placed at the calf. In this way we can measure the angle of the knee and the muscle activity.

Figure 1: System review of product design.

The width of each bracelet is 3cm and the thickness is 2cm while the diameter is adjusted according to the body mass of the user (different diameter between upper leg and calf). The bracelets will be in three number sizes, small, medium and large.The main bracelet has four surface electromyograph sensors (EMG) for tracking the activity of quadriceps-hamstring muscles. Both have an inertial measurement unit (IMU) sensor for tracking the knee angle, flexible PCB circuit accommodates the microcontroller unit (MCU) and a flexible battery with wireless charging and a capacity estimated to be sufficient for 2 days (500mAh each one, Li-Ion). The BLE protocol ensures tiny power consumption and deep sleep modes when the device is not in use. The material is mainly a skin-friendly elastic fabric combined with soft elastic bump plastic material and are dust and splash proof resistant, so the user can safely use it in indoor and outdoor exercises. In the following table 1 we present how each component contributes to monitoring user's daily rehabilitation program (all the components except EMG sensor and USB-C charging are used on both bracelets).

I/O	ID	Component type	Role
Input	**EMG**	*Surface Electromyography (on main bracelet)*	Valuating and recording the electrical activity produced by quadriceps-hamstring muscles. Monitors the strength of the muscles to reach the levels before the injury
	IMU	*Inertial Measurement Unit*	IMU sensor is a combination of accelerometers and gyroscopes. Real time knee angle tracking for avoiding the of risk of knee re-injury.
Output	**VBR**	*Vibrator Motor*	Receive feedback alerts when knee angle becomes risky.
	LED	*RGB LED*	Feedback to user interaction.
MC Unit	**MCU**	*System on Chip (SoC) Microcontroller Unit (MCU)*	Microprocessor with integrated Bluetooth Low Energy (BLE) chip.
Power	**BAT**	*Flexible Battery (Li-Ion)*	Flexible battery with wireless charging and a battery life for 2 days.
	USB-C	*USB-C charging (on main bracelet)*	USB-C charging
	DOCK	*Charging Dock*	Charge wirelessly the bracelets through a Dock

Table 1: Electric components and their relation on the bracelets.

Mobile Application and User Experience

The wearable device combined with the smartphone application offers a digital service for both the patient and the PT. This application and hardware ecosystem provide a friendly context for the successful completion of the rehabilitation program and it significantly reduces the risk of possible re-injury. Through this system PTs will get smart insights and data about the current status of the patients. These will allow PTs to make personalised adjustments for each patient and monitor the process of rehabilitation program in order to speed up recovery. The end-users will also be able to monitor their recovery through the smartphone application in real time. By sending motivational notifications, the users will be informed about various events including the necessity of taking breaks during exercises and the appropriate intensity and repetitions for each exercise. The main focus here is to improve user adherence and to avoid injuries. Visualisation techniques including charts and infographics will be used to provide a friendly interface to the actual data.
The interface is intuitively designed following Google's Material Design guidelines to provide a reliable and pleasing user experience.

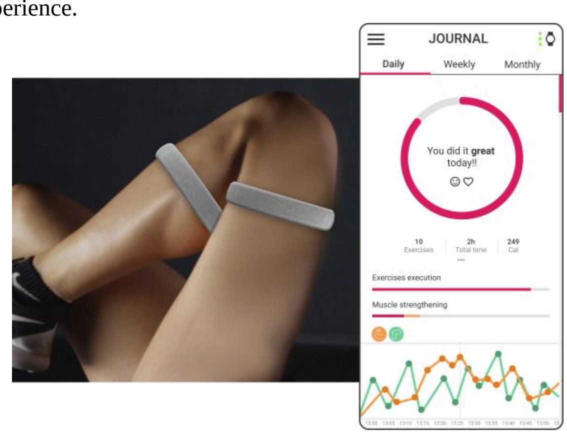

Figure 2: User Interface and concept design use.

The main features of the smartphone application are: *Timeline* activity, in which the user can view the daily rehabilitation program, how many days are left for completing the program as well as the duration of the daily activities (UI1 at Fig.3). All the activities/exercises must be performed in the order set by the PT. *Exercise* activity, includes all the necessary elements for tracking the execution of each exercise (UI2&UI3 at Fig.3). After the completion of patient's physical examination, the PT determines through the digital service: a) the initial and final position (knee angle degrees), b) repetitions and c) number of sets that the user can support for each exercise. Additionally, there is an interactive guidance (tutorial) for depicting the implementation of each exercise, live feedback for knee angle degrees and charts for illustrating the knee angle and the muscles activity throughout the duration of the exercise (gradient colors indicate the risk factor). After each daily exercise session execution, a *Progress* activity appears with exercise stats, tips and feedback collection for better results (UI4 at Fig.3). *Journal* activity presents the log of the recovery (daily, weekly, monthly data), how successfully the patient performed the exercises, what is the amount of muscle recovery (strength), the amount of time it took to execute the exercises, motivational feedback such as achievements record and calories burned (UI5 at Fig.3). Other activities include functionalities such as: Treatment Plan, Virtual PT communication, Wearable settings.

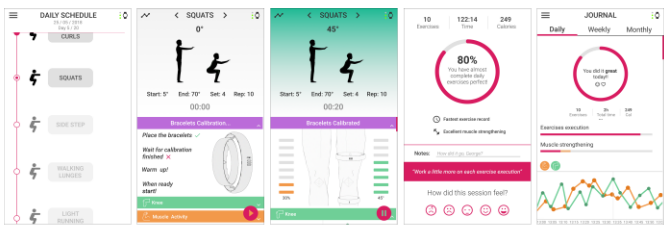

Figure 3: Concept design of User Interfaces.

5 Evaluation and Results

At this stage of the project, a fully functional mockup (with physical and digital objects) was developed to monitor the angle of the knee and muscle (quadriceps – hamstring) activity. A smartphone application also designed for digital data viewing. A knee bandage was used for adjusting all the physical components in one complete set. The components that we used were: *Arduino Micro, MyoWare Muscle Sensor Kit, Flex Sensor, Bluetooth Sensor HC-05, Battery Li-Po 450mAh*. The mockup collected data from the knee, angle and muscle activity, that where transferred to a smartphone application for the user to interact and observe.

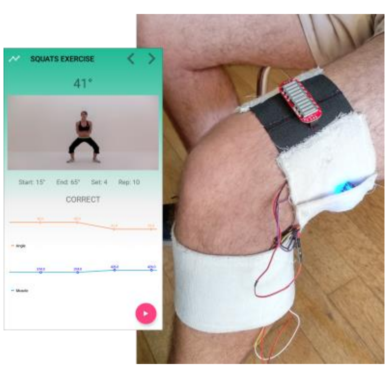

Figure 4: Working prototype and its application interface.

The preliminary evaluation was based on a formative study with experts. The main objective was to examine the effectiveness of the preliminary design concept and collect information that will be used later on for the design of the actual prototype. We developed high-fidelity interfaces, running as a native application for Android, for the test subjects to evaluate. The usability testing process was informal between participants and test moderator. A total of four (n=4) user subjects were recruited to evaluate the prototype, one with anterior cruciate ligament rupture. User subjects performed a specific scenario with a number of tasks (t=20) related to FF [29]. Evaluation findings showed that the user subjects believe the digital wearable assistive system is useful during the execution of rehabilitation program. The system enhances the communication between patients and PTs as the physical prototype helps in monitoring and tracking. The smartphone application motivates users to adhere in their HEPs through user interaction. A number of issues related to the functionality and the form of the physical product of the early concept were observed. These include inaccuracies in angle calculation by the flex sensor which in turn confused users when they performed their exercises. Moreover, visualisation techniques of muscle activity during the exercises were not clear for most users. They requested a clearer interface compared to the summary graphs presenting the overall performance at the end of the programme.

6 Conclusion and Future Work

In this paper we described the design and the formative evaluation of a wearable system to assist people with CL rapture during their rehabilitation. We presented a set of requirements, the design decisions, the prototype of both the physical product and its software ecosystem and an evaluation with expert users.

There is a number of points that need to be further explored in order for a fully working prototype to emerge. These are mainly related to the feasibility and effectiveness of using wearables in rehabilitation and specifically HEPs. Important is to identify the role of the caregiver and the interface components and functionalities for participating remotely in the rehabilitation programme by managing, observing and assessing remotely patients' activities. Finally, it is important to further investigate motivational techniques and educational mechanisms for supporting self-efficacy and improving adherence during HEPs.

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