ATP: Aqua Therapy for Patients, a New Approach for Water Rehabilitation Follow-up with Connected Devices Linked with a Serious Game

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Abstract: Rehabilitation is a public health issue that addresses the societal and economic problem of loss of autonomy. Following a rehabilitation program may require an effort of movement and consistency for people with motor difficulties who sometimes lack interest in this physiotherapy period that is difficult to concentrate on. Thus, the ATP project proposes to improve the use of lower limb water rehabilitation by proposing a device combining the use of sensors for direct biofeedback and serious game aspects to increase patient motivation. The equipment will facilitate real-time monitoring and learning of rehabilitation. In addition, the device will allow the physiotherapist, through information management and processing software, to program personalized movement sequences based on each patient's pathology and monitor their progress throughout the rehabilitation session and throughout the entire program. At each stage, the needs of professionals and patients will be taken into account to ensure the success of rehabilitation processes.

1 INTRODUCTION

In the world, there are around 69 million traumatic injuries, being traumatic brain injuries (TBI) one of the leading causes of death and disability, about 15 million strokes and it is expected that 1 in 6 people will have a stroke (Johnson and Griswold, 2017).

These problems, most of the time, cause motor disorders like lower limbs incapacitating, and this incapacity places a burden on health services due to long physiotherapy period and sometimes permanent disability of patients. Therefore, it is necessary to find solutions that allow these patients to recover in a quickly, effectively and less painful way.

1.1 Aquatic Therapy

The use of aquatic therapy was born after the Second World War as a re-education technique for certain neurological deficits such as polio (Kemoun and Watelain, 2006). The aquatic environment thus seems to have a large potential for rehabilitation, whether for the treatment of acute traumas, musculoskeletal disorders, neurological problems, orthopaedic or rheumatological problems, cardiopulmonary problems or by keeping fit in the face of chronic diseases. Thanks to its clinical adaptability, the practitioner can program therapies adapted to a population of patients with diverse pathologies.

From a physiological point of view, immersion in an aquatic environment has many biological effects, using all homeostatic systems (Becker, 2009). They are generally classified in 4 categories: hydrostatic mechanics composed in particular of Archimedes' thrust, hydrodynamic mechanics, the physiological effect of water (temperature), and psychological.

Indeed, according to Archimedes' theorem "Anybody immersed in a fluid [...] undergoes a vertical force [...] opposed to the weight of the displaced fluid volume". This means that when the patient is immersed up to the belly button, his perceived weight represents 50% of his actual weight. This allows the patient to feel lighter and...
freer, and thus reassured. These effects combined with the hydrostatic pressure also allow an elevation of the centre of gravity as well as an easing of the maintenance of static and dynamic equilibrium.

In addition, the hydrostatic pressure, associated with the viscosity of the medium, is at the origin of exteroceptive sensory stimuli. The immersion of the body in the water seems to cause a better perception of the position of the patient’s limbs. On the same idea, resistance to displacement seems to enhance both exteroceptive and proprioceptive information, thus allowing a better awareness of the "overall body pattern during movement". Moreover, by a mechanism still little known, it seems that the hydrostatic pressure, by intensive stimulation of the baresthetic receptors, would cause an analgesic in the joints. This theory is known as gate control technology to reduce the gravitational forces and gravity treadmills using differential air pressure. They all take advantage of this supportive environment. The technologies combine large boxes equipped a with treadmill on the ground or specific water resistance jets. The water level is adjustable in term of height in most cases. As a consequence, the exercise can be adapted to adults as well as children.

The hydrostatic pressure would also intervene on the breathing phenomena by acting on the resistance at the level of the diaphragm and on the swelling of the abdomen. The temperature of water also plays a role on the re-education. Indeed, the heat relaxes the muscles, because of dilation of blood vessels (Kemoun and Watelain, 2006; Becker, 2009).

Some studies (Rahmann et al., 2009; Stockton and Mengersen, 2009; Villalta and Peiris, 2013) have wondered what are the interests and disadvantages of potential wounds of postoperative aquatic therapy. According to these articles, the aquatic therapy would improve functional rehabilitation and would not increase the risk of adverse effects related to wounds after surgery.

The article (Giaquinto et al., 2010) describes that after a total knee intervention, aquatic therapy seemed beneficial because all treated patients had lower arthritis pain scales. In addition, patients reported a pleasant sensation of safety, allowing them to be rehabilitated more quickly.

In summary, what we know is that at the musculoskeletal level, the use of water properties allows a better rehabilitation through several effects:

- Musculoligamentary circulation by increasing oxygen supply and improving metabolic waste disposal;
- Decrease in potential edema;
- Modular muscle toning;
- Reduction of joint constraints by a work in discharge;
- Relaxing and analgesic effect of immersion, especially on chronic pain;
- Sensory stimulation, in the case of a significant postural deficit, for example;
- Stimulation of afferent fibres in subjects whose sensitivity is impaired;
- Proprioception and better perception of the body diagram;
- Improved motor coordination and balance by using the inertia of water during central nervous system dysfunction;

The articles, devoted to the study of the benefits of water, demonstrate that the fields of application of immersion in water are very wide and may be suitable for a large part of the population: athletes, paediatrics, disorders mentioned above, geriatrics and obese persons.

1.2 Existing Solutions

On the market of water rehabilitation, several companies propose therapy pools and underwater treadmills. They all take advantage of this supportive environment. The technologies combine large boxes equipped a with treadmill on the ground or specific water resistance jets. The water level is adjustable in term of height in most cases. As a consequence, the exercise can be adapted to adults as well as children.

The applications are diverse: sport performance purposes, recovery from injuries, weight challenge, gait re-education after neurological disorders, strokes… Only a small proportion of these kind of products are registered as medical devices and they do not record clinical parameters. The association of such devices with connected gaming has not been seen on the market for the moment.

Other systems exist on the market, like anti-gravity treadmills using differential air pressure technology to reduce the gravitational forces and therefore permit moving without pain, reproducing a kind of “levitation” environment.

The common goal of these technologies is a feeling of body weight reduction and a minimized joint impact. It is a great alternative to land-based therapy, especially in the early stage of recovery.
1.3 Serious Game

1.3.1 Concept

Defining a serious game is not something easy because of the amount of classifications and criteria. If there is only one thing to remember about it, this should be that the serious game combines the enjoyment experience of the game, with a useful objective. According to (Alvarez and Damien, 2003), it could be summarized by the following relationship:

Serious Game = Utilitarian function(s) + Video Game

The serious game concept is, above all, a game which engenders satisfaction and challenge to the player. The ‘serious’ goal can be related to many fields such as defense, health, education, learning, ecology and so on (Alvarez and Damien, 2003). At the end, the outcome can be sending a message, sharing knowledge or developing and improving skills.

In the Malone’s theory (Malone, 1981), three characteristics compose an intrinsically motivation instructional environment: the challenge, the fantasy and the curiosity.

- The challenge is provided by a goal whose attainment is uncertain, depending of the difficulty for example. The goal is one of the reasons why a player wants to play. It uses the player’s skills and takes part in the fantasy of the game.
- The fantasy is, in a manner of speaking, the story of the game and how it is related. A game can have an infinity of universes – real or not – and equally many manners to relate it.
- The curiosity is a subtle balance between the player expectations’ and the game evolution.

1.3.2 Place of the Serious Game in Rehabilitation

Many studies in virtual reality or based on serious games have shown the interest of these environments that offer the opportunity to significantly expand the variety of applications with a positive effect on patient motivation (Sorita et al., 2013). In other articles, authors raised this problem of motivation particularly because of the repetitiveness of the exercises (Rego et al., 2010). For instance, (Burke et al., 2009) talk about the “lack of patient interest in performing repetitive tasks and in ensuring that they finish the treatment program”. It is indeed recognized that a greater involvement of the patient in his re-education will lead to an interest in dedicating more time to the activities that constitute it. So it seems obvious that using serious game increase the patient involvement. Not directly in the rehabilitation, but in an enjoyable activity that makes him focus on something else less boring or less exhausting.

To (Fovet et al., 2017), there are three important levels for feedback in a therapy program: the game feedback, the psychophysiological feedback and the therapist feedback. Thus, in rehabilitation, the use of serious games could not only improve the motivation of patients, but also deliver patients returns in a funny way regarding their performance or in response to unsuitable movements. Thus, this promotes learning or reprogramming of movements sequences required to perform the requested activity. The psychophysiological feedback refers to the biofeedback that delivers a real time information about the patient, inside the serious game and during his session. A serious game is only one more tool in the physiotherapist’ rehabilitation toolbox that is why the therapist’ feedback is essential to support and to advice the patient (Fovet et al., 2017).

2 ATP: AQUA THERAPY FOR PATIENTS

The project was born as part of the ClinMed2018 Summer School granted by EIT Health. The purpose of this 10-days course was to conceptualize an innovative medical device from the needs identified during our first three days in a hospital immersion. The following days of this program gave us an up-to-date general perspective of the life cycle of a medical device: from the initial concept until it reaches the market. These different lectures given by professionals in the field of medical devices as well as our different school backgrounds, within the team, allowed us to develop our idea to a concept of medical device.

It was at the Garches hospital, in the rehabilitation department, that our idea of aquatic therapy was born. Indeed, it is during the visits of the different units of the hospital that some clinical needs have been identified. After neurological disorders (such as post-stroke patients with hemiparesis, foot drop, paralysis and spasticity for example), traumatic injuries or surgeries, it may be difficult to regain mobility in the beginning of recovery. In fact, because of long joint
immobilisation, fear and pain is usually felt when training mobility. To facilitate the rehabilitation early process, water environment offers several advantages as explain in introduction. Furthermore, balneotherapy pools are only available in big functional rehabilitation centres and private clinics that can afford and support associated maintenance costs. However, smaller clinical facilities have not enough space and resources to use hydrotherapy. Therefore, some patients have to travel kilometres to find this specific solution. Our turnkey solution will allow the practitioners to benefit from hydrotherapy without requiring a swimming pool.

The ATP device consists of four main parts:
● Water chamber where the patient will enter, and the water rises until the adapted level;
● Connected devices: a carpet with force sensors inside and waterproof cameras;
● Serious games for the patient to interact with;
● Software and database, which integrates the interface used by the physiotherapist and doctor and a cloud.

Therefore, in this section, it is described in detail the main parts of the device.

2.1 Water Chamber
The water chamber (figure 1) consists of three parts of glass walls (the lateral sides and a door), and a stainless-steel part comprising the removable screen and the corners. It includes the connected carpet that is sealed at the bottom of the chamber. Two removable handrails are present on each side, so they can be adjusted to the right height of each patient. They allow the patient to maintain the balance ensuring his safety. The cabin can be filled with an adjustable quantity of water according to the size of the patient and the body clinical target. The water can reach the hip of a patient.

It also includes a reservoir and water filters that can be placed in a different room to allow better space management. The connection between the reservoir and the chamber is made through plumbing.

2.2 Connected Devices
The ATP is equipped with a carpet with the force sensors inside and waterproof cameras. These devices allow to test and track the patient’s movement.

2.2.1 Connected Carpet
It is composed by an underwater force platform. Such platform has been identified in the market. The sensors that composed the force platform will be placed in the floor to avoid no contact with water, and the electronic parts will be placed in the waterproof box outside the water chamber. The collected information will then be sent to a computer device via Wi-Fi for data processing.

This arrangement, presented in figure 2, is related to the movements that the patient must perform in accordance with the serious games (that will be explained next) projected on the screen. It can be done to place his left foot forward, on the right or take a step back. It is the same thing for the right foot. In addition, it is possible to take more support on one of his feet and the sensors in the platforms will explain in real time the plantar pressure of the patient. In addition, the carpet can become unstable, according to the willingness of the physiotherapist with a moving system, in order for the patient to train his balance and posture. The carpet allows to have information of the

Figure 1: Representation of the water chamber of the ATP device.

Figure 2: Representation of feet placement.
pedobarography and stabilometry of the patient, in order to know the pressure exerted on the plantar level, and if he places his foot correctly on the sensors. The articles (Rosário, 2014; Skopljak et al., 2014; Notarnicola et al., 2018) show that pedobarography seems to be a good method for monitoring effects of rehabilitation in a non-invasive way. In fact, it’s important to have the evolution of the patient, this device can allow knowing if the patient takes confidence and improves his way of walking.

2.2.2 Waterproof Cameras

The chamber will be equipped with cameras that will track the patient's movements. These devices will enable the practitioner to ensure that the patient performs the right movements and the right placements. It also allows following the evolution of the rehabilitation in addition to the information given by the sensors present in the carpet. The cameras allow a following of the angles at the knees and ankles.

It may be composed by a set of 4 cameras at 4, located at the middle of each side, to get the best viewing angles for each leg.

2.3 Serious Game

2.3.1 Game Concept

The serious game integrated into the ATP device would be the following: the person in rehabilitation will discover the world through the theme of travel and culture. This thematic is quite universal and intergenerational.

The principle of this serious game is to display on the screen in front of the patient a world map. At the beginning, it can be assumed that the player is in France or in one town in particular. The goal is to travel all around the world, to visit countries and towns and to discover different cultures and famous locations. Challenge is brought by the way of transport and the new countries and places to unlocked. The patients’ curiosity is maintained by the cultural aspects: customs, history, and so on.

2.3.2 Relation between the Game and the Rehabilitation

Conception of the serious game must be adapted according to the rehabilitation needs. This one will use the patient movements in the water and his pressures on the carpet to move on the serious game map. Depending on the movements done by the patient, the four motion cameras and the sensors in the carpet will record the positions of his legs and of his feet. All that information will be transmitted to the practitioner’s software and analyse in one hand by the computer to move forward in the serious game; in another hand, by the professional to evaluate the progression of the patient in his rehabilitation.

2.4 Software and Database

The last part of the device will be mainly dedicated to the physiotherapist and will have a double utility. The first is to centralize the information gathered during the session, process and share it and the second is to manage the application of the serious game for the patient's rehabilitation session.

2.4.1 Software

Recording and the processing of the data from the sensors and in a bigger dimension the storage and exploitation of these in medical purposes is the first goal of the software.

The software has to be able to restitute information understandable by the practitioner, in particular the physiotherapist. For instance, a representation of the gait and a restitution of where and how the patient puts his feet on the carpet (pedobarography). That is very important to the professional as an indicator of good evolution of the rehabilitation. In addition, this could be a source of advices if the patient’s movements are not correctly done.

The second function is the management of the serious game. From the interface of the software, a specific part will be dedicated to the Serious Game. Like that, before each session, the practitioner just will have to set the serious Game (movements the patient has to work on, duration of the exercises, difficulty, and so on). At the end, the progression of the patient is recorded as a track of his work. The progression will be symbolized by the bonus and the evolution of the patient in the gameplay.

2.4.2 Database

Another aspect of the device is to centralize all the information gathered by the sensors and the cameras during the rehabilitation. Two objectives for that: the big data and the share of the information about one patient to all the health care professional around him. Indeed, we already know that only a little part of this kind of information is shared between the medical staff. The hypothesis is the more the
professionals will have interaction around one patient in rehabilitation, the more his rehabilitation will be efficient in all its dimensions (physical, psychological, and so on…).

The expression ‘Big data’ has to be understood like a big amount of information about the gait in the rehabilitation context in order to improve the knowledge of the professionals; a better comprehension of its mechanic can be helpful to find indicators to predict the healing.

2.5 Our Added Value

Our product aims to allow the motor rehabilitation of people suffering from motor disorders such as neurological disabilities, strokes, traumatic injuries (ankle, knee, and hip), orthopaedics post-operative. The project has four main added values:

- The use of the water for the re-education;
- The use of the sensors to follow the evolution of the rehabilitation of the patient;
- The water chamber which allows a more practical rehabilitation for the patients in private clinics;
- And the serious game that makes the re-education more attractive and motivating for the patients.

Indeed, the novelty of this system is based on the use of a serious game for rehabilitation in water. There are a lot of benefits to use the water for rehabilitation, as we said before. The water is use as a supportive environment. In fact, the weight sensation is reduced, enabling to train the motricity in a painless way, because of the decrease pressure on joints and bones to resume support on the legs faster. Water resistance enhance also the muscular rehabilitation. So, thanks to its qualities, water can allow people who do not stand on their feet on the ground, to regain self-confidence inside the water which allows them to relearn how to walk. Finally, all the benefits of water can reduce the time of rehabilitation in comparison with a conventional therapy (Geytenbeek, 2001; Honda and Hiroharu, 2012).

The second added value concerns the combination of different sensors that track the patient's progress in real time. In other words, his plantar pressure will be used to verify that he correctly places his foot thanks to the plantar platforms, and the waterproofs cameras for tracking the patient's movement.

The value added by the box comes from the fact that there are not enough balneotherapy centres. Patients often have to walk miles to find a centre that allows this kind of rehabilitation. The idea would be to equip private clinics with these boxes to allow the patient to have easier access. These boxes require the presence of physiotherapists to check the progress of the session and adjust the serious game to the pathology of the patient.

Finally, the serious game makes the therapy more attractive to the patient, and possibly reduces the orthopaedic recovery time.

3 DEVELOPMENT PLAN

3.1 Regulatory Strategy

The registration requirements and thus the technical file are related to our medical device class. Each country has its own classification rules and we will focus here on European directives. So, according to the clinical use we provide for the device, one of the first things is to define the class of the medical device, following the VIII Annex classification of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical device (European Parliament and Council of the European Union, 2017).

The intended purpose is the water rehabilitation of the lower-limb. It’s a non-invasive device, with transient duration (less than 60 minutes). The device depends on a source of electrical energy; so it is an active device, has monitoring elements and includes software. Considering all these elements, ATP is a Class I medical device.

As consequence, the conformity evaluation procedure only depends on the manufacturer’s responsibility (no intervention of the notified body). As the device has a measure function, a production quality assurance must be implemented.

3.2 Validation and Verifications Tests

In order to validate and ensure reliability, the device must be properly tested to verify the operating conditions, effectiveness and safety of its functionalities. Therefore, verification and validation tests must be carried out.

The verification tests try to determine whether the result at each stage in the development process satisfies the needs of the next phase. The primary objective is to detect as many errors as possible, whether conception, design or assembly errors. There are several tests being that for this equipment include:
• Measurement of the specifications of the components: functioning of the sensors (sensibility of the sensors, transmission capacity...), verification of the proper placement of the waterproof cameras to follow the movements of the patient optimally, and so on;
• Measurement of the speed of water filling in the cabin and the adjustment of the temperature, as well as the sliding of the bars;
• Overheating: check if the device does not overheat with continuous use throughout the day;
• Power supply: check if all devices are properly powered;
• Study of adverse conditions: verify if the system is minimally resistant to conditions like stress and shock;
• Software study: verify if the application does not block with a continuous use throughout the day.

Validation tests are performed during or at the end of the development process to assess whether the specified requirements of the device or a component are met. These tests, carried out according to a complete risk analysis, include validate the effectiveness and precision of the sensors to acquire measurements and also the usability of the device.

The usability tests will include a large patient population to test the use of the chamber (patient size, weight, age). These tests aimed to ensure issues like the dimensions of the devices, the sensors functioning on the human body. It will be necessary to validate the use of these devices by clinical tests.

For the software, we need to do several tests based on users’ stories to prove the usability of it, with wireframes first, then with a prototype. The aim is to ensure ourselves of the usability of the software.

For the serious game they must be developed and designed with a strict collaboration between physiotherapists, patients and developers, so the specific needs of both, the professional, the patient and the rehabilitation will be respected in the specifications book. About the tests of the serious game, it is the same process as for the software: personas, experience maps, wireframing and prototype.

Finally, all along the life of the system, risk matrices will be used to ensure its proper functioning and to prevent the emergence and neutralisation of possible risks.

3.3 Economic Model

In order to have a successful business strategy, we identified who are the stakeholders and what is the clinical pathway. The physiotherapist and private clinical centre may profit from the investment on our product for different reasons. First, if we consider the doctor-physiotherapist link: the physiotherapist equipped with the device may be recommended and thus privileged by the patient for his treatment. Considering the patient-physiotherapist link: this attractive and powerful equipment brings an added value for the physiotherapist renown thanks to fattest recovery; on this point is also important to refer, as a future step, that one trend of the rehabilitation market relies on the “digital” or “e-tech” enthusiasm in our modern society, above all for the sporty community. Indeed, consumerism begins to reach healthcare and the patients ask for the best care.

Therefore, as we intend to sell our device directly to private physiotherapy clinics, we are going to adopt a B2C relationship. For that, we would disclose our products from unpaid channels, with the issuance of a website with information and product specifications, and paid channels, such as medical equipment exhibition, direct email contact and congresses. In order to have a business strategy, we decided to adopt the Continuity Income Method Business Model - along with the sale of the product (chamber of water and sensors and a user formation), there would also be a loyalty of the cloud and assistance of the product with an annual fee (subscription fees).

4 CONCLUSIONS

As water provides essential advantages for early physical rehabilitation like buoyancy, weightlessness and confidence for moving, underwater rehabilitation is highly valued. To meet to the demand of physiotherapists without aquatic facilities, the ATP project proposes to develop water rehabilitation for the assessment and training of lower limbs capacities with connected devices toward measure effort and feedback. The project also depends on the use of a serious game which is not only to improve the motivation of patients but also to deliver biofeedback in a fun way about their performance or in response to potential incorrect movements.

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