DEVELOPMENT OF MEDICAL EQUIPMENT FOR FUNCTIONAL THERAPY: CAPABILITIES OF A NEXT-GENERATION MECHANOTHERAPEUTIC SIMULATOR

DESENVOLVIMENTO DE EQUIPAMENTOS MÉDICOS PARA TERAPIA FUNCIONAL: CAPACIDADES DE UM SIMULADOR MECANOTERAPÊUTICO DE ÚLTIMA GERAÇÃO

DESARROLLO DE EQUIPOS MÉDICOS PARA TERAPIA FUNCIONAL: CAPACIDADES DE UN SIMULADOR MECANOTERAPÉUTICO DE PRÓXIMA GENERACIÓN

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ABSTRACT
In traditional physiotherapy, aimed primarily at the rehabilitation of biological tissues, over the past ten years, there have been changes in the field of mechanobiology. The studies have shown the effect of physical forces on cells and tissues, which led to the realization of the need to update the old model of therapy. Mechanotherapeutic simulators are being actively developed, and as the research results show, effective mechanotherapy requires constant updating of devices that, due to the development of technology, could better and more accurately affect the stimulation of the restoration of the biological tissue. The present article is devoted to the development and description of a next-generation mechanotherapeutic simulator that provides a more convenient control interface compared to existing analogs. The article describes its mechanical and electronic components, as well as software. The prospects of application of the Industry 4.0 concept in the field of medical equipment for functional therapy are shown in the example of the developed simulator.

Keywords: mechanotherapy, microcontroller, wireless communication, Industry 4.0.

RESUMO
Na fisioterapia tradicional, voltada principalmente para a reabilitação de tecidos biológicos, nos últimos dez anos, ocorreram mudanças no campo da mecanobiologia. Os estudos mostraram o efeito das forças físicas sobre células e tecidos, o que levou à constatação da necessidade de atualização do antigo modelo de terapia. Simuladores mecanoterapêuticos estão sendo desenvolvidos ativamente e, como mostram os resultados da pesquisa, a mecanoterapia eficaz requer atualização constante de dispositivos que, devido ao desenvolvimento da tecnologia, possam afetar melhor e com mais precisão a estimulação da restauração do tecido biológico. O presente artigo é dedicado ao desenvolvimento e descrição de um simulador mecanoterapêutico de última geração que fornece uma interface de controle mais conveniente em comparação com os análogos existentes. O artigo descreve seus componentes mecânicos e eletrônicos, bem como o software. As perspectivas de aplicação do conceito da Indústria 4.0 na área de equipamentos médicos para terapia funcional são mostradas no exemplo do simulador desenvolvido.

Palavras-chave: mecanoterapia, microcontrolador, comunicação sem fio, Indústria 4.0.

RESUMEN
En la fisioterapia tradicional, dirigida principalmente a la rehabilitación de tejidos biológicos, en los últimos diez años se han producido cambios en el campo de la mecanobiología. Los estudios han demostrado el efecto de las fuerzas físicas sobre las células y los tejidos, lo que llevó a darse cuenta de la necesidad de actualizar el antiguo modelo de terapia. Los simuladores mecanoterapéuticos se están desarrollando activamente y, como muestran los resultados de la investigación, la mecanoterapia efectiva requiere una actualización constante de los dispositivos que, debido al desarrollo de la tecnología, podrían afectar mejor y con mayor precisión la estimulación de la restauración del tejido biológico. El presente artículo está dedicado al desarrollo y descripción de un simulador mecanoterapéutico de próxima

generación que proporciona una interfaz de control más conveniente en comparación con los análogos existentes. El artículo describe sus componentes mecánicos y electrónicos, así como el software. Las perspectivas de aplicación del concepto Industria 4.0 en el campo de los equipos médicos para terapia funcional se muestran en el ejemplo del simulador desarrollado.

Palabras clave: mecanoterapia, microcontrolador, comunicación inalámbrica, Industria 4.0.

1. INTRODUCTION

According to the modern definition, mechanotherapy is a type of therapeutic physical culture involving the use of mechanotransduction mechanisms to stimulate the restoration of biological tissues (bones, tendons, and muscles) (Khan, Scott, 2009).

This medical term was coined by the doctor T. Billrot in the middle of the 19th century to name the method of treatment of many diseases already established by that time applying massage and medical gymnastics. The main provisions that should guide the doctor, applying mechanotherapy, were developed earlier by the Swedish scientist Heinrich Ling. On the initiative of his follower Gustav Zander, the world's first medical and mechanical institute was founded in Sweden in 1865, where studies were conducted on the effect of physical exercise on various changes in the human musculoskeletal system.

Today it is known that the therapeutic effect of mechanotherapy is achieved due to the phenomenon of mechanotransduction, that is, the process during which the body converts mechanical stress into cellular reactions that contribute to structural changes in tissues (Duncan, Turner, 1995; Durieux et al., 2007).

Studies (Biykuzieva et al., 2020; Gevorkyan et al., 2020; Major et al., 2020; Grishin et al., 2019) distinguish the features of mechanotherapy as a functional therapeutic and preventive therapy, among which the most important, in our opinion, are:

- deep biological adequacy: according to the concept of kinesophilia, movement is an integral innate biological function and the most important mechanism of body integration;
- comprehensiveness: the impact is carried out directly or indirectly on all organs through all levels of the somatic and autonomic nervous, and endocrine system;
- no negative effects provided the correct dosage of exercises;

- the possibility of long-term use of mechanotherapy for both treatment and prevention of diseases.

The present article is devoted to the description of the mechanotherapy simulator of the lower extremities, intended for the treatment of a condition after a bone fracture. Such an injury requires prolonged immobilization of the injured area, which entails the risk of contractures, or joint stiffness. In this case, the effect of mechanotherapy is that the flexion and extension of the limb are performed directly by the simulator, without the participation of the patient's muscles. This allows a patient to painlessly develop the joint for several hours a day. Due to the constant flexion and extension of the joint, the metabolism in the injured area is accelerated and the soft tissues are restored to normal.

2. METHODS

The research was conducted at the Pitirim Sorokin Syktyvkar State University (Russia) to develop the next generation of mechanotherapeutic simulators. The research was conducted in two stages.

Stage 1. For this purpose, we have selected the main mechanotherapeutic simulators that are used in medical institutions for mechanotherapy of the lower extremities, intended for patient’s treatment after a bone fracture.

The following main mechanotherapeutic simulators were considered.

2.1 Artromot-k1

One of the most popular mechanotherapeutic simulators today is the ARTROMOT-K1 produced by ORMED (Germany), which is a unique offspring of the DJO Global brand (USA).

ARTROMOT-K1 is used for continuous passive motion (CMP) development of knee and hip joints. Using this device in clinical practice, as well as by private individuals on a rental basis, is an important addition to a therapeutic treatment.

Joint development using the ARTROMOT-K1 mechanotherapeutic simulator is applied primarily to prevent contractures, to accelerate the process of restoring painless joint mobility, as well as to promote rapid recovery with a good functional result.

This mechanotherapeutic device allows developing the knee joint for stretching and flexion in the range of -10-120°; for the hip joint – in the range of 0°-115°. The device can be used for both the left and right legs without a special adjustment.

The main disadvantages of the ARTROMOT-K1 simulator are:

- Inconvenient control interface, which is a wired remote control;
- Complex user interface;
- The operating modes must be set each time before starting the procedure.

2.2 Fisiotek 2000

The devices of the Fisiotek 2000 series (Italy) include six models, ranging from models that allow developing all three joints of the lower extremities and ending with narrowly focused models that are designed to develop only the knee joint. The body of the devices is made of a durable alloy. This guarantees to prevent deformations of the housing after long service life. The devices contain modern electronic equipment and mechanical components. The device is driven by DC motors, which are controlled by the microprocessor.

Individual programmable patient memory cards can be used to control the device. This option allows the patient to start the next session without additional configuration. The initial series of joint movements can be performed at smaller amplitude, thereby preparing the joint for the main rehabilitation session. These models of devices can be used to develop limbs with a length from 61 to 115 cm with an amplitude from -5 to 135^{o}.

The main disadvantages of the Fisiotek 2000 are:

- Inconvenient control interface, which is a wired remote control;
- The maximum speed of the device operation does not meet the requirements of medical professionals;
- Bulky body of the device.

2.3 Ormed-flex

The Russian simulator ORMED-FLEX for passive impact on the knee and hip is designed to train the musculoskeletal system of the lower extremities. The simulator is used in sports and health clubs, as well as cosmetology offices. The main disadvantages include:

- Inconvenient control interface, which is a wired remote control;
- Limited continuous operation time;
- Bulky body of the device.

Stage 2. After analyzing the solutions available on the market, a set of requirements for a new-generation mechanotherapeutic simulator was determined and a prototype of such a device was developed. The main key features of the new device are:

- Modern user-friendly interface that would allow patients to determine intuitively the operation program of the simulator;
- Rejecting the wired remote control as a potentially unsafe factor in the mechanical system;
- The possibility of integrating the simulator into the information system of a contemporary clinic, including the possibility of remote control and monitoring of the device using a smartphone or computer.

3. RESULTS

Proposed solution

The developed mechanotherapeutic simulator consists of three main blocks: mechanical, electronic, and control unit. The visual appearance of the device is shown in Fig. 1.

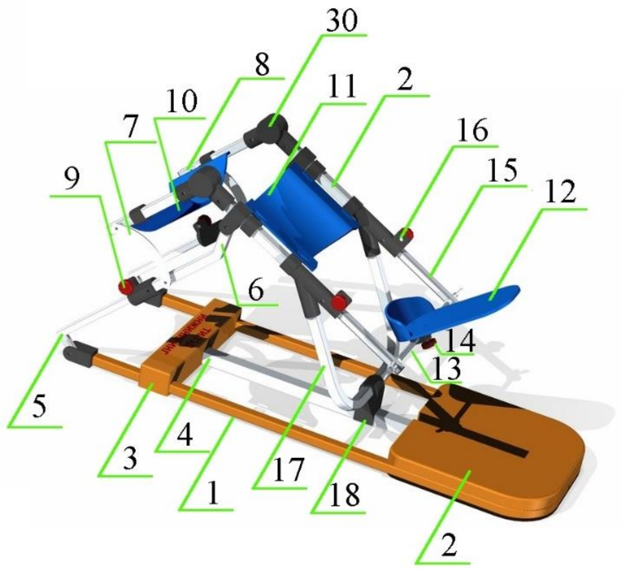

Figure 1. The visual appearance of the mechanotherapeutic simulator
Source: research data

The mechanical unit contains an immovable base (1), a block with electronics in a protective housing (2), a base (3) for bearing support and an end sensor, a casing for a screw (4), a rocker arm (5) pivotally fixed on an immovable base, and a transmission. The transmission is made in the form of two mechanisms containing the first (6), second (7), third (8) links. The link (6) can move along the rocker arm (5) and be fixed by the fixation elements (9). The hip support (10) is fixed on the third link. The lower leg support (11) is fixed to the frame (2). The foot support (12) is fixed on the axis (13), secured by fixing elements (14). The distance between the knee joint and the foot is regulated by a link (15) and fixed by fixing elements (16). The link (17) is connected to the frame and the carriage (18). The carriage is connected to the nut of the ball screw transmission. The ball screw transmission (19) is mounted on supports (20) located on the base (3) and inside the electronics unit (2). Pulley (21) at the end of the ball screw transmission is connected to the pulley (22) by a toothed belt (23). The pulley (22) is fixed to the gearbox shaft (24). The gearbox is driven by an electronically switched brushless DC motor (25). The frame with the patient's foot, mounted on it moves resulting from the operation of the motor, which transmits movement through the gearbox, belt drive, and ballscrew.

The mechanotherapeutic simulator is set in motion using an electronically switched brushless DC motor. Direct control of the motor is carried out by the driver, which is controlled by the control circuit. The control circuit is based on the PIC16F88 microcontroller. For correct operation, the device is equipped with several sensors, from which data are transmitted to the control circuit. Also, MCP4725 digital-to-analog converter is used to set the motor speed. Communication with the outside environment is provided by the ESP-12E Wi-Fi module based on a processor with an ESP8266 core (Cameron, 2021), which exchanges data with the control circuit. A block diagram of the interconnections of the device components is shown in Fig. 2.

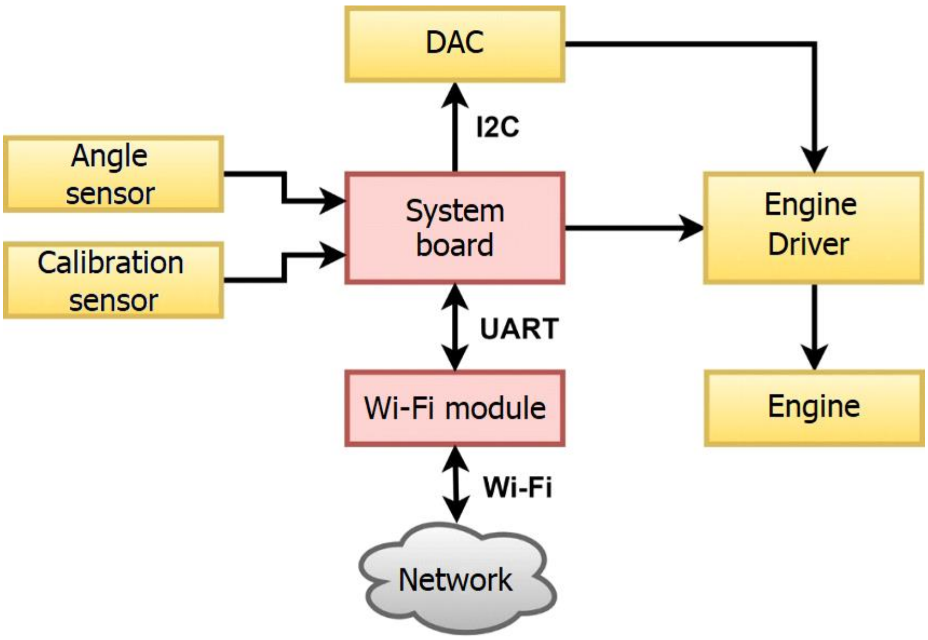

Figure 2. Block diagram of the electronic components of the device
Source: research data

Data and commands from the operator are transmitted to the local Wi-Fi network and through the Wi-Fi module are sent to the control circuit and stored in it. After receiving a command from the operator to start, stop, set, or change the operating mode of the device, the control circuit sends electrical signals to the motor driver to set the movement direction and speed of the motor. The control circuit can accept data on several operating modes and execute them sequentially one after another. The motor driver is used to control the power supply to the motor, which ensures the rotation of the motor in the desired direction and set rotation speed, as well as ensure reliable operation and high efficiency. The motor driver provides smooth acceleration and braking at the beginning and end of the movement, or when changing the movement direction. The control of the leg bend angle occurs through a special angle sensor. The bend angle sensor is connected to a twisted pair control circuit. Using the sensor readings, the control circuit changes the operating mode of the motor through the driver to ensure the necessary conditions for the procedure being performed.

Interface and communication

The device operates in Wi-Fi access point mode by default (Tanenbaum, Feamster, Wetherall, 2021), i.e. it creates its own network to which one can connect using a device that supports connection and data exchange via Wi-Fi. Such Wi-Fi devices of the operator are mobile phones, slates, laptops, and PCs. After connecting to the device via a Wi-Fi network in conjunction with a special program, installed on the user's Wi-Fi device, one can work with the device by transmitting commands and data that set the operating mode of the device, as well as receive information about the current state of the device.

In addition, it is possible to connect a mechanotherapy simulator to an existing Wi-Fi network.

The control program of the system implements the possibility of simultaneous operation with several devices with individual operation settings for each device. The devices must be connected to the same Wi-Fi network and controlled by the operator's Wi-Fi device. For the convenience of working with a group of devices, the operator can assign unique names that are stored in the non-volatile memory of the devices.

A personal computer or a mobile device can serve as the control node of a mechanotherapeutic simulator. An application with a convenient graphical interface has been developed for mobile devices (Fig. 3). The application allows working simultaneously with several devices and is a server to which devices are connected in client mode.

Figure 3. User application interface

4. DISCUSSION

The control model, applied in the developed device allows the device to be used in keeping with the spirit of contemporary trends in the field of mechanotherapy (Huang et al., 2013) and the modern concept of Industry 4.0 (Frolov et al., 2019) due to the following features:

- Forming a hardware ecosystem that can be included in the information system of a modern hospital, mechanotherapeutic simulators cease to be isolated devices. This allows optimizing the work of hospital staff, and increasing the safety of their use due to the visual representation of the current state of the devices;
- Mechanotherapeutic devices can be controlled by the operator remotely via the Internet, including when the patient is situated in a remote geographical location;
- Automatic accumulation of patient information using sensors can provide initial data for subsequent statistical analysis and training of smart algorithms that would select the trajectory of rehabilitation for future patients with similar symptoms.

5. CONCLUSION

Despite the traditional mechanical part, the mechanotherapeutic simulator, developed at the Pitirim Sorokin Syktyvkar State University demonstrates new approaches in creating interfaces of medical equipment and informatization of the medical industry in general. Probably, in the future, by analogy with smart home technologies, smart hospital technologies will become widespread, which will include an ecosystem of interacting medical devices that flexibly implement effective trajectories of patient treatment and rehabilitation.

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