Invent a Removable Orthosis with the Ability to Prevent Foot Drop and Venous Thrombosis and Maintain Muscle Contraction

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Abbreviations: WHO: World Health Organization; ICUs: Intensive Care Units; VTE: Venous Thromboembolism; PTE: Pulmonary Thromboendarterectomy; DVT: Deep Vein Thrombosis

ABSTRACT

Background: Intensive care includes the care of patients with life-threatening diseases, under the supervision of the most skilled personnel with advanced equipment and facilities, which includes all sensitive care related to the patient’s life. Complications of hospitalization in special wards include foot drop, deep vein thrombosis and atrophy, and decreased muscle strength. The aim of this study is working on approaches for preventing Foot drop, deep vein thrombosis and atrophy and decreased muscle strength.

Methods: This project started with a new researcher idea then by searching in the scientific content of articles and book, the title and proposal the project was compiled with opinion of the supervisor. Then model of the device was designed in collaboration with graphic & mechanical engineers Fianccy. The main tool was invented by the researchers.

Results: Results of this study and other surveys can be one of the most effective ways to prevent ankle foot drop, deformity of the toes, muscle atrophy improve blood flow from the lower to the upper and monitor vital signs and maintain the strength of the foot muscles. Also using orthesis can decrease it significantly. Besides, modifying the preventive policies such as producing instruments like Removable orthosis is recommended.

Keywords: Orthosis; Foot Drop; Venous Thrombosis; Muscle Contraction; Prevent

Introduction

From the perspective of the World Health Organization (WHO), health is the science and technology of disease prevention, providing medical services for immediate diagnosis, treatment and development to address problems. Safety is one of the most important aspects of health care systems [1]. Increasing the quality of work, consequently, increases the accuracy and improvement of the treatment process, the speed of the treatment process and
also patient satisfaction [2]. Intensive care includes taking care of patients with life-threatening diseases, under the supervision of the most skilled personal, with advanced equipment and facilities, which includes all sensitive care related to the patient’s life [3,4]. A significant part of the treatment system’s effort is focused on being able to provide the best services to its patients in the shortest time and at the lowest cost. Intensive care units (ICUs) have an important place due to the high human and economic costs that they can incur for the health care system [5,6].

Patients with problems such as diabetic ketoacidosis, hypertensive emergency, non-accidental self-poisoning, heart failure, ischemic heart disease and cerebrovascular disease and respiratory conditions can be mentioned [7-9]. Numerous studies have been performed to identify the increasing mortality factors of patients admitted to the ICU. Infectious shock, age, smoking and nosocomial infections are among the factors that increase mortality in ICU wards [10,11]. A comprehensive study of UK hospitals showed that the mortality rate of patients admitted to ICU wards is about 20.6% [12] and that of Singapore public hospitals is 9.4% [13]. Complications of hospitalization in the Intensive Care Unit include foot drop, deep vein thrombosis[14], muscle atrophy [15] and so on. Venous thromboembolism (VTE), including deep vein thrombosis(DVT) and pulmonary thromboendarterectomy (PTE), is a public health problem that results in 250000 hospitalizations per year in the United States [16,17]. On the other hand, one hundred to fifty thousand people are hospitalized every year due to a benign and treatable disease, but die due to pulmonary embolism, while with prevention, the death of these patients can be prevented [18].

Risk factors for this disease are immobility, cancers, myocardial infarction, respiratory failure, surgery, trauma, obesity, use of female hormones and inherited coagulation disorders [19]. Another complication of hospitalization is “foot drop”. Foot drop or foot prolapse is a condition in which a person is unable to perform the dorsiflexion joint function properly due to weakness or paralysis of the anterior tibialis muscle or other muscles originating in the peroneal nerve. Foot drop can be unilateral or bilateral. Symptoms such as pain, weakness, and numbness are sometimes seen with this complication [20]. Diagnosis of this complication is easily possible by physical examination, but the use of imaging techniques and electromyography can also help to examine this complication more closely [21]. Today, there are various treatments to control foot drop, which considering the cause of this complication, the appropriate treatment method is adopted. Among the available treatments for prevention and correction of foot drop, physiotherapy, electrical stimulation and teaching the most common treatments using ankle foot orthosis [22].

Other complications of hospitalization in the intensive care unit include muscle atrophy [15], bed sores, etc. At present, according to the subject and results of research, one of the ways to prevent and reduce complications in hospital wards is to produce and use a mobile orthosis with the ability to prevent foot prolapse and venous thrombosis and maintain muscle contraction. In the following, we will talk about its structure. This idea has been registered in the Patent Organization of Iran under invention number 103769.

Methods

This project started with a new researcher idea that by searching in the scientific content of articles and books, the title and proposal the project was compiled with the opinion of the supervisor. Then model of the device was designed in collaboration with graphic & mechanical engineers Fiancy. The main tool was invented by the researcher. By mechanic engineer and solid work the design of this tool with professional software with academic-theoretical proposal researchers (Mahmoudi and Mohammadheik) about making a tool for the purpose of preventing foot drop, deformity of toes, muscles atrophy, improvement of blood return from distal to proximal organs and keep the function of vain valves, assessment of vital signs and keep the power of foot solid muscles and prevention from muscles atrophy. This idea is designed by softwares and then the file of this designing was transferred to laboratory by researcher and work mechanic engineer in order to hardware designing and maquette. The structure of orthosis was discussed in terms of all angle’s morphology, measurement of figure based on standards and again after changing s figures and ,measurement was redesigned by software expert.

Figure 1: According to Figure 1
1. Orthotic body
2. Mechanical lock
3. Electric leads.

This mobile orthosis with the ability to prevent foot drop and keep the function of vain valve and assessing the vital signs is
composed of (mechanical lock: 3×2cm, body: 40 cm length, pulse sensor: 0.5×0.5 cm, pulse oximeter sensor: 0.5×1 cm, inflatable inner layer R: 12cm, outer layer R: 15cm, electrical message transmitter leads: R: 1cm, insole: 25cm, removable hinge R: 2cm, connector between inner layer and air pump R: 2cm). Orthosis is made up of upper and lower sections which after right locating (positioning) of foot, two sections will be connected to each other by mechanical lock (according to Figure 1, number 2). for motion of foot in its range of motion (ROM), first removable hinge (according to Figure 7, number 11) is connected to monitor screen which is separated from orthosis by a wire. All normative motion for foot’s motion (foot’s dorsal flexion, foot’s sole flexion, inversion, overination) will be done by a program which is designed on screen and by choosing each motion, message will be transferred to removable hinge (according to Figure 2, number 11) by a wire and by moving the orthosis, the foot moves in the desired direction and according to instruction given to program, the foot remains at desired posture for specified period of time (5s) and returns to its initial posture again.

**Figure 2:** According to Figure 2
1. 7- outer layer of orthosis
2. 8- inner layer of orthosis
3. 11- Removable hinges.

**Figure 3:** According to Figure 3
1. Air pump
2. LCD
3. Power on
4. Power off
5. Junction with interface.
Four foot motion (foot’s dorsal flexion, foot’s sole flexion, inversion and overtion) is done through a program which is programmed on the screen memory via removable hing, the duration of doing this motion, number of times, the amount of foot’s rest until next move. For preventing deep vein thrombosis (DVT) and maintaining the one way valve function, first the portable small air pump (according to Figure 3, number 1) which is available in the market is connected to the connector between air pump (according to Figure 4, number 4) and inflatable inner layer (according to Figure 2, number 8) by an air tube through transferring air from pump to inflatable inner layer the action of inflating and emptying takes place. Of course the number of times, intensity of wind pressure is defined by screen (according to Figure 4, number 6) available on pump’s body(according to Figure 3, number 1) and applied on foot, which this action causes standard pressure(17 mmhg) on one way valve and it causes continuity and helping blood circulation and prevents from the reduction of one way valve function.
According to Figure 6

1. 9- pulse Oximeter sensor
2. 10- Pulse Sensor.

Also electrical leads (according to Figure 1, number 3) are connected to the desired position (according to Figure 5, number 5) by a wire and after connecting to tennes machine (impulse maker machine) by making impulses causes electrical stimulation of muscles and prevents muscles failure and atrophy that voltage intensity, duration of muscle stimulation, number of stimulation are controlled and done by screen (according to Figure 5, number 2) and planning is done. According to location of the sensor in the upper part of orthosis (according to Figure 6, number 10) number of dorsal pedis pulse is measured and shown on the screen. Also by placing pulse oximeter sensor on the upper part of orthosis (according to Figure 6, number 9), the amount of oxygen saturation is shown on the screen. By making movable orthosis and due to structure and muscle electrical stimulation prevents reduction of muscle contraction, atrophy and foot drop and causes maintaining valve function and the amount of oxygen saturation is studied through dorsal pedis pulse sensor and pulse oximeter sensor and can prevent the accuracy of many diseases and the death caused by them.

**Discussion**

This research has been done in the field of medicine and medical engineering. Due to the extent of the foot drop and Deep vein thrombosis when providing medical care to the drug, the use of preventive equipment is felt to prevent this problem. Due to the innovative design of this design, Used to prevent ankle foot drop, deformity of the toes, muscle atrophy, improve blood flow from the lower to the upper and improve blood flow from the lower to the upper and monitor vital signs monitor vital signs and maintain the strength of the foot muscles. The advantages of this plan include moving the foot in four directions (flexion of the back of the foot and flexion of the sole of the foot and inversion and oversight), the ability to plan the number and time of movements, check vital signs in the lower limb, prevent reduction of contraction Muscles, preventing blood stasis and thrombosis in the lower extremities, preventing atrophy and muscles mass. Also, according to the research of Esfandiari et al (2017), a study entitled Literature Review of the Effect of Ankle-Foot Orthosis on Gait Parameters After Stroke [23] and Alnajar et al (2020), with Title Advances in neuroprosthetic management of foot drop [24] and prenton et al (2018), with Title FUNCTIONAL ELECTRICAL STIMULATION AND ANKLE FOOT ORTHOSES PROVIDE EQUIVALENT THERAPEUTIC EFFECTS ON FOOT DROP [25], and this research, the use of preventive equipment to prevent Ankle foot drop, toe deformity, muscle atrophy, improving blood flow from the lower to the upper and maintaining pigeonhole valve function and monitoring vital signs and maintaining leg muscle strength is suggested.

**Results**

Results of this study and other surveys can be one of the most effective ways to prevent prevent ankle foot drop, deformity of the toes, muscle atrophy, improve blood flow from the lower to the upper and monitor vital signs and maintain the strength of the foot muscles. Also using orthesis can decrease it significantly. Besides, modifying the preventive policies such as producing instruments like Removable orthosis is recommended. We are ready to work with all institutions and individuals in the fields of economics, education, research and health and startups for this idea. If you wish, please contact us via masoudmahmoudi515@ymail.com.
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