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Research article

Upper limb active orthosis for post-stroke rehabilitation at home

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Abstract: Home-based rehabilitation post-stroke can help to improve the recovery of upper limb motor function, increase patient motivation for training, lower rehabilitation costs, and optimize post-stroke care for clinical staff. Rehabilitation in acute and chronic post-stroke phases with task-specific, repetitive training has been shown to improve upper limb function. Rehabilitation technology such as robotic devices can provide such physical training and facilitate consistent rehabilitation means. However, the large dimensions of such devices, high costs, and various technical aspects are factors that can limit usage only in rehabilitation facilities. This paper presents the design of a lightweight and fully portable active orthosis that provides passive mobilization of the elbow and has an innovative mechanism for supination and pronation of the forearm. A 3D model was constructed, considering the biomechanical requirements of the joints and overall feasibility for home use. 3D scanning and printing were used to develop and produce the device. The usability of the active orthosis was evaluated on 5 healthy volunteers using the System Usability Scale, which revealed very good results. The active orthosis presents easy set-up and operation, making it an excellent tool for at-home rehabilitation.

Keywords: active orthosis; upper limb; rehabilitation; biomechanics; 3D printing

1. Introduction

In stroke patients, the prevalence of upper limb (UL) impairment is high, as it is reported to be present in 40 up to 77.4% of cases [1,2]. The affected limb can present various degrees of motor impairment characterized by muscle weakness, spasticity, lower speed and active joint range of motion, and also the inability to perform coordinated movements [3,4]. This affects the ability to perform daily activities thus reducing the patient's quality of life [5]. Further developments are needed since less than 15% of patients with initial UL impairments reach complete recovery of UL function [6].

Rehabilitation after stroke is key in the recovery of the UL, in both acute and chronic post-stroke phases [7]. Task-specific, repetitive training has been shown to improve UL function [8]. Rehabilitation at home may further improve recovery of UL motor function, increase patient motivation for training, lower rehabilitation costs, and also optimize post-stroke care for clinical staff. However, it is imperative that the rehabilitation solutions be accessible and simple to use, as already challenges in post-stroke care at home are considerable in comparison to clinical settings [9].

Rehabilitation technology such as end-effector and exoskeleton robotic devices can provide such training and have shown great results in improving motor functions in the UL [10-12]. A limitation of end-effector robots is that the position of the joints in the UL which are not in contact with the robot is not fully controlled. This is important as passive or active mobilization of the UL must be done while ensuring normal joint motion. Exoskeleton robotic devices can provide control of the joints during movement because they present corresponding mechanical joints and are worn on the UL. However, in both types of robotic devices, many lack portability [13]. Some devices used for rehabilitation are stationary systems that need to be placed on the ground or can be mounted on the patient's wheelchair or a table [13,14]. Also, in the operation of these devices, a therapist may be needed [14]. Consequently, the devices need a designated space and specialized personnel for set-up and rehabilitation. Large dimensions of such devices, high costs, and various technical aspects are factors that can limit usage only in rehabilitation facilities.

Post-stroke care imposes difficulties and important challenges for the patient's family as well [15,16]. Financial pressure or the degree of patient disability represents stress factors that have an impact on the family's quality of life [15]. Challenges faced by the patient's family negatively affect recovery rehabilitation adherence [15]. Moreover, conventional physical rehabilitation after stroke can be demanding for therapists in many aspects due to the duration, intensity, or type of training sessions. Also, as stroke-related disability cases are high, a shortage of specialized staff for physical rehabilitation may bring additional challenges [17].

Active orthosis could facilitate rehabilitation of the UL at home. These devices are actuated orthosis with mechanical joints that ensure motion in the UL joints during mobilization. An example of such a device is the Myomo MyoPro® (Myomo Inc., Cambridge, MA, USA), which is a powered orthosis that has shown great results in improving UL motor function [18]. The Myomo MyoPro® also comes in the Motion W type system which provides means of rehabilitation for the forearm, to perform supination and pronation movements. Other designs have been proposed to facilitate the rehabilitation of the UL, but only concern the elbow joint [19-22]. Many robotic rehabilitation devices provide training for flexion-extension of the elbow, but few do for supination-pronation of the forearm [14]. There have also been some theoretical 3D models developed that provide means for supination-pronation of the forearm [23,24]. However, there is still a need for active orthosis that provides rehabilitation for the elbow and forearm that can easily be manufactured, have low costs, small dimensions, and weight, and be portable. As mentioned earlier, the costs of rehabilitation for the UL must be decreased, and as the costs of production of such devices can be high, it may also reflect in accessibility and cost of treatment for the patient.

This paper presents a 3D printed UL active orthosis that provides passive mobilization of the elbow and, through an innovative mechanism, it also provides mobilization of the forearm in supination and pronation. The developed device is lightweight, fully portable and uses affordable materials, thus an excellent tool to be used in post-stroke at-home rehabilitation. 3D modelling, scanning and printing were used in the design process, while considering important elements such as portability of the device, safety, and ease of overall operation during usage. An evaluation of the usability of the active orthosis was performed on a group of 5 healthy volunteers using the System Usability Scale (SUS), which revealed very good results.

2. Materials and Methods

2.1. Joint kinematics and 3D design

In the first part of the design process the joint kinematics were analysed and kinematic diagram was made (Figure 1). Following, a 3D technical solution was constructed in CAD software Fusion 360 (Autodesk).

The elbow joint is considered a hinge type joint where movements of flexion and extension can occur.

To comply with the kinematics of the elbow, the position of the elbow flexion-extension axis in the frontal plane was considered to have a distal medial inclination of 2.5º [25]. The axis of the forearm with respect to the axis of the humerus describes a 9º angle, which is the carrying angle used in the design of the active orthosis.

To follow the type of joint, a hinge type articulation was designed (Figure 2). Two uprights situated laterally, are articulated in the hinge joint, lateral to the elbow. The articulation is made via two ball bearings connected with a shaft. An inner and outer ring profile and 4 mm Ø rolling elements create a bearing that further stabilizes the mechanism. To further increase stability, the servomotor support is attached to the arm upright and connected to the shaft through one of the bearings. Flexion-extension of the elbow is achieved using a servomotor and bevel gears that transfer the torque to the hinge joint. The range of movement provided is 0º (elbow extended) to 120º (elbow flexed).

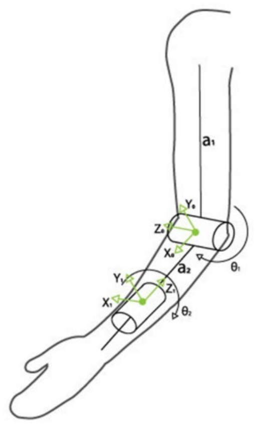

Figure 1. Kinematic diagram of the elbow and forearm joints.

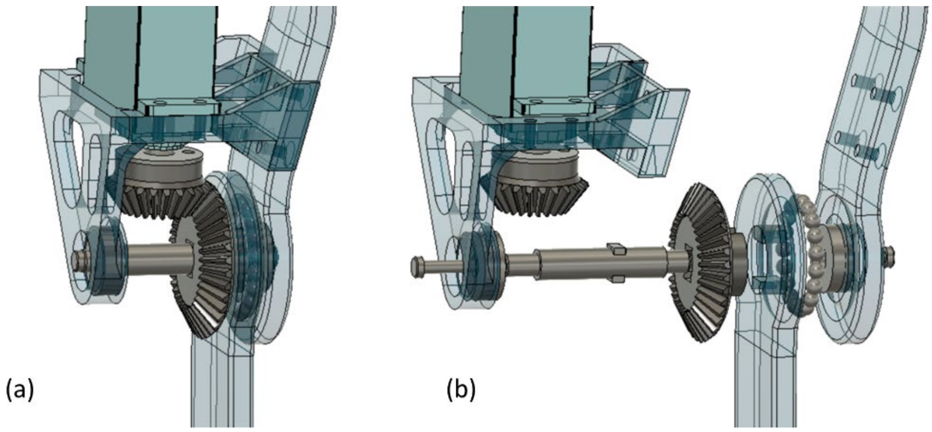

Figure 2. (a) Mechanism for flexion-extension movement of elbow joint. (b) Exploded view of mechanical joint.

2.2. Forearm mechanism design

The mechanism developed for the supination and pronation of the forearm features an innovative, safe, and easy-to-use design. The mechanism is composed of a double helical gear system (Figure 3). Smaller gears are placed on the inner and outer part of the primary gear, allowing a guided and stable rotation. Metal gear shafts and ball bearings were used for the smaller gears. At the wrist, a supporting cuff attaches to the primary gear. Torque is transmitted through a compound gear train which is driven by a servomotor, providing maximum range of motion for the forearm movement, 90º pronation/supination. In designing the supination-pronation mechanism, we analysed the cross-section geometry of the distal forearm. The width of the distal forearm was considered as the starting point of the diameter used. The C-shaped structure has been commonly used in other orthosis designs as it allows for easy donning and doffing. However, closing the system was needed because, during use, the primary gear would be exposed, with the risk of being caught in clothes or contamination of the lubricant used. Thus, a mobile part attached to the casing was made, allowing for it to be opened during doffing and donning and closed when using the orthosis, with a Velcro strap.

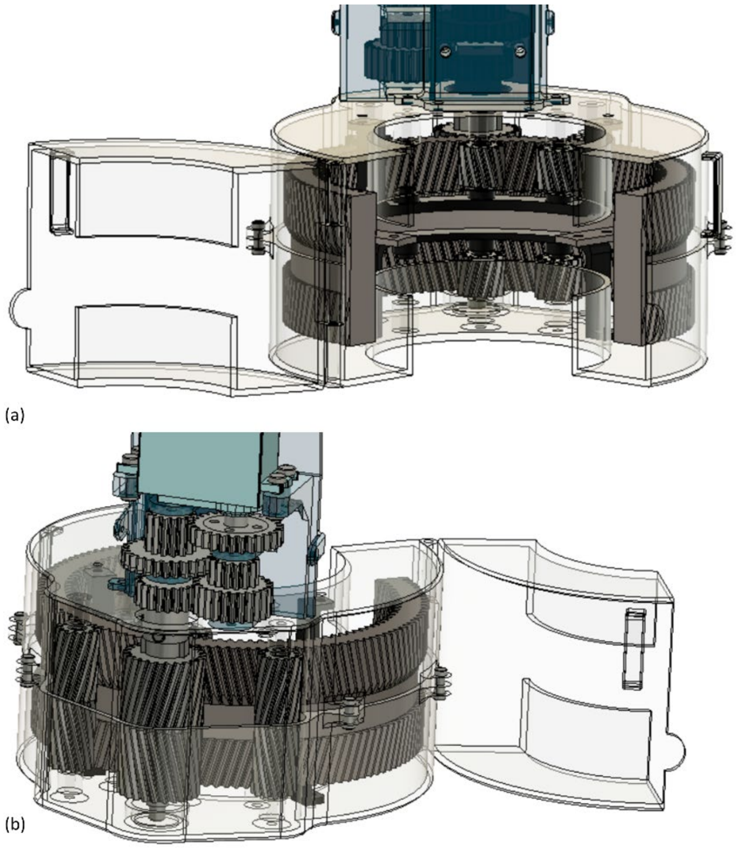

Figure 3. (a) Detail view of the supination-pronation mechanism. (b) Outer view of the mechanism.

2.3. 3D modelling of brace cuffs

3D scanning of the UL was made using the Sense 2 3D Scanner (3D Systems), to design the brace cuffs that support the arm and distal forearm. The scan was imported in CAD software Fusion 360 (Autodesk) to obtain an editable solid shape. As the form of the section varies both in arm and forearm, an oval shape was found to be a better fit. Measurements of circumference were also made to double check the obtained 3D cuffs.

2.4. 3D printing

After 3D modelling of the orthosis, parts were printed using PRUSA i3MK3S 3D printer. The majority of the parts of the orthosis are 3D printed with the exception of parts such as bearings, shafts for bearings or screws. To ensure good mechanical properties of the printed parts, appropriate printing parameters were chosen. Infill density ranges between 10% for smaller parts such as gears to 60% for uprights or servo supports. For the latter, to further increase resistance, gyroid infill pattern was chosen. While printing and assembling parts, layer height was adjusted. Parts with complex small details were printed using a smaller layer height of 0.15 mm to ensure correct layer adhesion and better printing results. Larger parts such as uprights or cases were printed with a 0.3 mm layer height. The brace cuffs were printed using PLACTIVETM filament (Copper3D, Santiago, Chile), diameter 1.75 mm, tensile modulus 3600 MPa, with antimicrobial properties. The rest of the parts were printed using a polylactic acid polymer (PLA) filament, PLA Premium Filament (Formfutura), diameter 1.75 mm, tensile modulus 3145 MPa.

2.5. Device usability assessment

To further assess the feasibility for home use of the active orthosis, an evaluation of its usability was performed on a group of 5 healthy volunteers using the System Usability Scale (SUS). Each of the volunteers was given information about the purpose and functioning of the active orthosis as well as a demonstration of the capabilities of the device, after which they proceeded to complete the questionnaire.

The SUS is a standardized questionnaire with a five-point Likert scale [26]. It comprises 10 statements that focus on usability and how quickly and effortlessly the user adapts to the utilization of a novel device. These two concepts are key aspects in designing a rehabilitation device for home use, as patients need easy, straightforward technology that improves their quality of life. The SUS is scored from 0 – 100. When scoring the SUS, odd-numbered statements scores are subtracted by one, while even-numbered statements scores are subtracted from five, thus each item has a maximum score of four. All 10 scores are summed up and the total is then multiplied by 2.5, resulting in the SUS score.

3. Results

Figure 4 shows the 3D printed active orthosis that was made based on the 3D model developed. Approximate dimensions are also included, showing optimal design to promote usability and portability. The orthosis weighs approximately 1.09 kg from which the servos together weigh 2x72g = 144g, and the four rechargeable batteries a total of 4x50.9g = 203.6g.

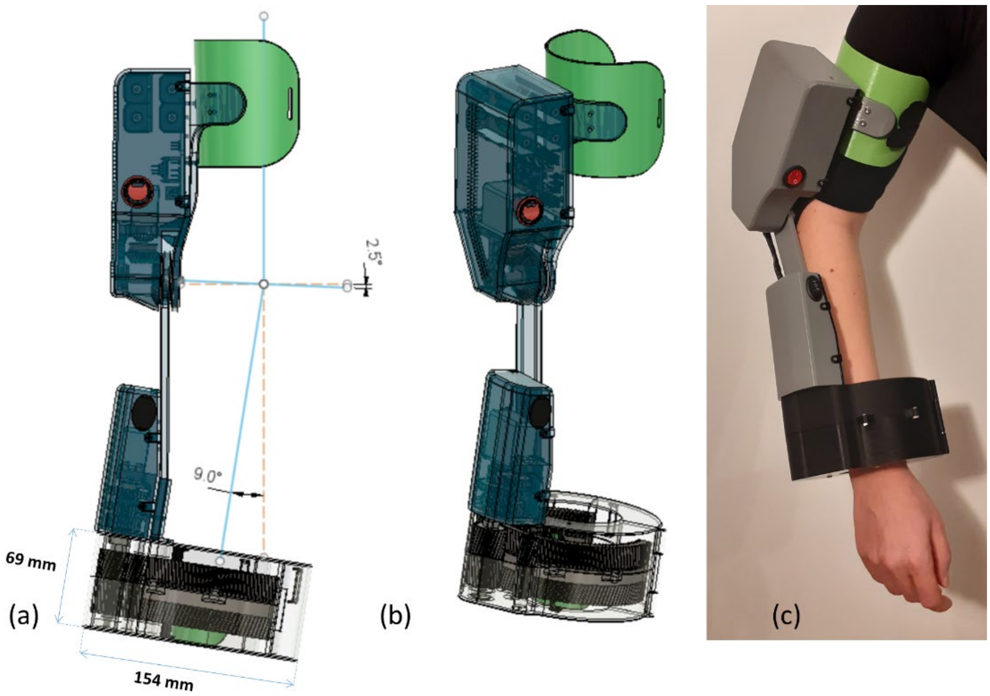

Figure 3. (a) Approximate dimensions of developed active orthosis and position of the elbow flexion-extension axis in frontal plane as well as the carrying angle used in the design. (b) Descriptive view of the 3D model of active orthosis. (c) 3D printed active orthosis.

This operate and programme the device, an Arduino Nano microcontroller placed on an expansion board was used. This microcontroller is an affordable board, that allows fast customization and modification of the operation of the device. The servomotors are used at the elbow level and the forearm level are commercially available programmable servos. Power supply consists of 4 18650 Li-Ion rechargeable batteries, 3600 mAh. This solution provided sufficient power to assess movement ensured by the orthosis while keeping the device fully portable.

Operation of the orthosis is done via two buttons. An on/off button of the orthosis is placed at the arm level where the patient can have easy access.

The second button is placed at the level of the forearm to allow the patient to switch between 3 options, I - elbow flexion-extension rehabilitation program, O - a neutral position, where the patient can rest, the orthosis is not moving, and II - forearm supination-pronation rehabilitation program. Figures 5 and 6 shows the position of the active orthosis and UL in flexion-extension of the elbow and supination-pronation of the forearm.

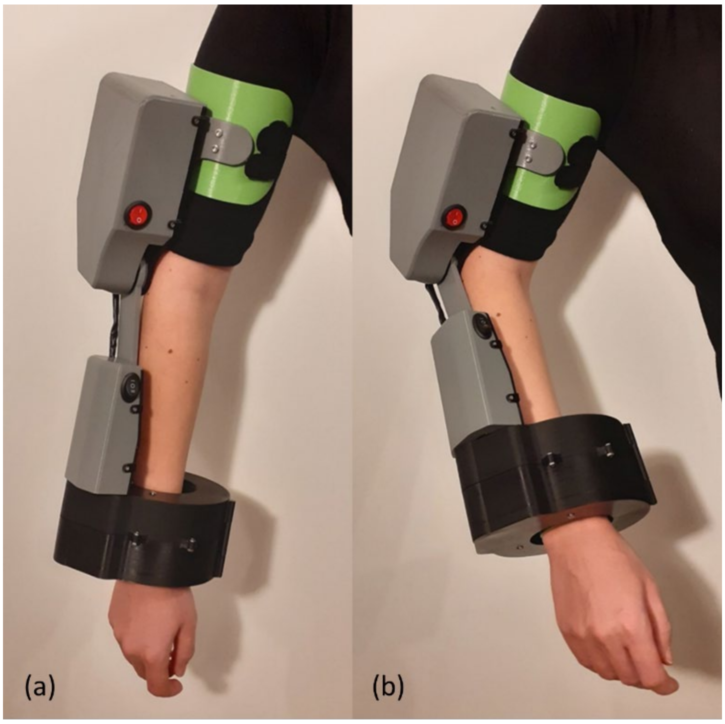

Figure 5. Position of the active orthosis and the UL in elbow (a) extension and (b) flexion.

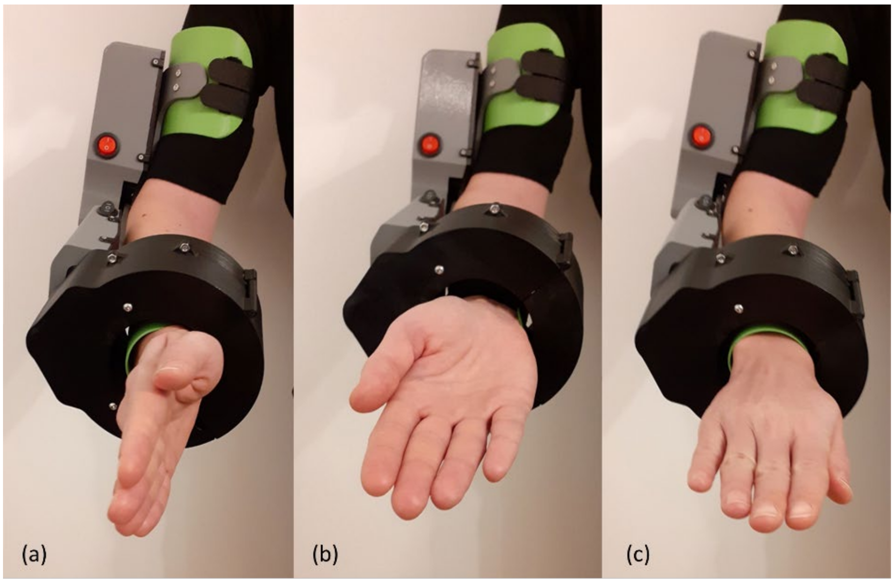

Figure 6. Position of the active orthosis and the UL in (a) neutral position of the forearm , forearm (b) supination and (c) pronation.

Figures 7 and 8 show results of the evaluation of the usability of the active orthosis, performed on the 5 healthy volunteers using the System Usability Scale (SUS). A raw average score was calculated for each item of the system usability scale to have a better overview of the results (Figure 7). Statements 2, 3, 5, and 8 show that the active orthosis is easy to use and its functionality is well designed. Results for statements 4 and 10 that focus on learnability show that the user can quickly learn to use the device.

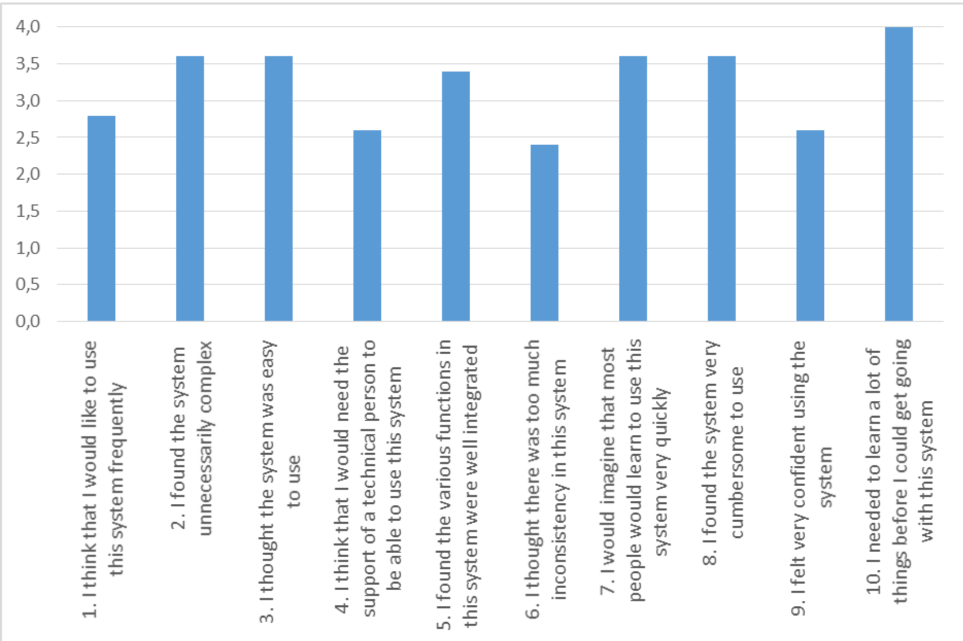

Figure 7. Raw average score for each item of the system usability scale.

The total SUS score was obtained for each of the volunteers, as can be seen in Figure 8. Scores ranged from 77.5 to 87.5, indicating a great level of acceptance, falling within the range of "good" to "excellent" on the overall usability scale. The overall average total SUS score was 80.5.

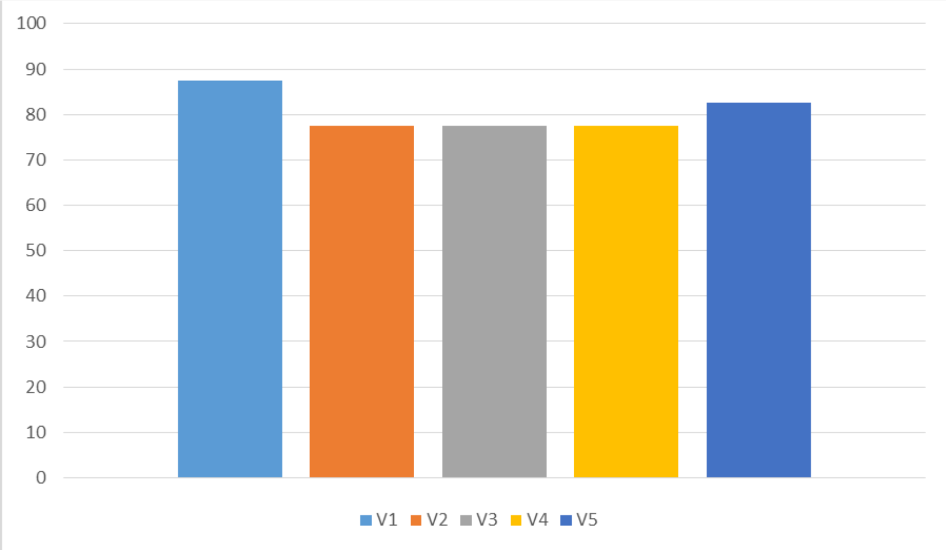

Figure 8. Total score of the system usability scale for each of the healthy volunteer.

4. Discussion

The Materials and Methods should be described with sufficient details to allow others to replicate and build on the published results. Please note that the publication of your manuscript implicates that you must make all materials, data, computer code, and protocols associated with the publication available to readers. Please disclose at the submission stage any restrictions on the availability of materials or information. New methods and protocols should be described in detail while well-established methods can be briefly described and appropriately cited.

The developed active orthosis is a lightweight, fully portable device that provides passive mobilization of the elbow joint and with the innovative supination-pronation mechanism, it also provides mobilization of the forearm. The gear system created for supination-pronation is a simple solution that reduces dimensions, weight of the device and ensures portability. Unlike other models proposed [23,24], the developed mechanism presents mechanical parts are encased to prevent contact with moving components and also protect the gear system. This ensures safety of the mechanism which is an important factor in designing a device for home rehabilitation. Velcro straps attaching the brace to the UL make donning and doffing facile, increasing user independence. Simplicity of the operation of the device eases the process of set-up, which at home, needs to be done with minimal training by either the patient or caregiver. In designing the active orthosis, it was crucial to consider the user's independence during its use. The easier it is to operate the device, the less external help the patient will need, increasing independence. Donning and doffing can easily be made as the attachments of the brace to the UL are done with Velcro straps. With the active orthosis, training sessions can be done in any part of the day, allowing for adequate rest. This is an important factor because stroke patients are often facing sleep challenges that have been shown to influence the outcome of recovery [27].

At the elbow, the particularities of the position of the flexion-extension axis as well as the carrying angle are parameters that are often oversimplified in the design of a device used for rehabilitation. In the proposed design of the active orthosis, the structure of the device follows the biomechanical requirements of the elbow and forearm, complying with joint kinematics, thus ensuring normal mobilization during rehabilitation.

The simplicity of the design and its focus on usability to provide an easy-to-use rehabilitation technology that can be used at home are validated by the great results of the SUS scores. Analyzing each statement, results show that the functions of the active orthosis are well integrated and the device is easy to use. The user can quickly learn and adapt to use the active orthosis. The total SUS scores obtained for each of the volunteers indicate a great level of acceptance, within the range of "good" to "excellent" on the overall usability scale.

The developed active orthosis uses affordable components and materials. The approximate cost for PLA Premium Filament, diameter 1.75 mm, 1000 g Premium Filament (Formfutura) is ~30€. The PLACTIVETM, diameter 1.75 mm, 750 g filament (Copper3D, Santiago, Chile) is priced at approximately 80€. With 3D printing technology a variety of materials can be used to produce the orthosis parts thus keeping manufacturing costs low [28,29]. Moreover, PLA is considered biocompatible and has multiple applications in the manufacturing of devices used in the medical field [28]. As the brace cuffs may come in direct contact with the patient's skin, it was important to ensure safety of the material used using the PLACTIVETM filament. This material is a polylactic acid polymer-based material that contains additives with copper nanoparticles which ensure antibacterial properties [29].

5. Conclusions

The developed device ensures passive mobilization of the joints in flexion-extension of the elbow and with the innovative mechanism for supination and pronation, movement at the forearm is achieved. The active orthosis is fully portable, lightweight and uses low cost materials and manufacturing. 3D printing and scanning technology was used to produce the active orthosis components. The usability of the active orthosis was evaluated on 5 healthy volunteers using the System Usability Scale, and revealed very good results. The design complies with kinematics of the joints, is safe during use, has easy set-up, and overall operation of the active orthosis, making is an excellent tool for post-stroke at-home rehabilitation.

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