Device customization with novel adhesive electrode

1Dr. Sameer Karpe, 2Dr. Kashinath Sahoo, 3Dr. G. Varadharajulu, 4Dr. Suraj Kanase

1PG student, Krishna College of Physiotherapy, Krishna Institute of Medical Sciences “Deemed To Be University”, Karad.
2Professor, Krishna College of Physiotherapy, Krishna Institute of Medical Sciences “Deemed To Be University”, Karad.
3Dean, Krishna College of Physiotherapy, Krishna Institute of Medical Sciences “Deemed To Be University”, Karad.
4Professor, Krishna College of Physiotherapy, Krishna Institute of Medical Sciences “Deemed To Be University”, Karad.

corresponding author’s e-mail address: kashipo@gmail.com

Abstract. The present research deal with the physical examination and analysis of an instrument that is ankle foot orthotic device. The physics of this device consist of calf piece; calf strap; a muscle stimulator; stimulator suspension including a press button with nylon strap; two adhesive electrodes; electrical wires; hinge joint; JBR outsole; foot piece; ankle strap; forefoot strap; rings; adjustable strap; press button; cold and hot pack pouch; a means to provide upward projection; & shank. The customized AFO device is characteristic in the sense that the adhesive strap being mounted on the rings so as to keep the plantar section of the foot piece in straight position and wherein the adhesive strap being made up by a combination of polyvinyl chloride, polypropylene and polyethylene wherein polyvinyl chloride, polypropylene and polyethylene is 1:1:2 by weight; wherein the cold and hot pack pouch being made up of 40.5 wt% water; 40.5 wt% ammonium nitrate, 4 wt% hydropropylmethyl cellulose and 15 wt% propylene glycol; and wherein the said electrode being made up of a hydrogel comprises of acrylic acid and N-vinylpyrrolidone. The overall result feedback is a feeling of increased muscle control, flexibility, and range of motion on using the device.

1. Introduction

Foot drop is common problem in stroke, multiple sclerosis, cerebral palsy patients, and in common peroneal nerve injury patient. Electrical stimulation and ankle foot orthosis (AFO) have been routinely used in individuals with foot drop to re-educate muscles which are weak and to keep ankle in neutral position. It is known that electrical stimulation is useful in treating individuals with foot drop. Sharif et al., [1] showed that the functional electrical stimulation (FES) is better in foot drop than conventional electrical stimulation (EMS) in stroke patients.

An ankle-foot orthosis, or AFO, is an orthotic device which is a support intended to control the position and motion of the ankle, compensate for weakness, or correct deformities of foot and ankle. AFOs can be used to support weak limbs, or to position a limb with contracted muscles into a more normal position [2,3]. In addition, AFOs are used to control foot drop caused by a variety of neurologic and musculo-skeletal disorders [4]. Due to the common use for addressing foot drop, AFO
has become synonymous with the term “foot-drop brace” [5]. AFO are easy to wear, and can be easily available at orthotics.

1.1. Research Objectives

The present study aims to provide a customized ankle foot orthotic device with an effective hot and cold pouch unit for improving foot drop of a patient selected from strokes, multiple sclerosis, cerebral palsy patients and common peroneal nerve injury.

i. To provide a customized ankle foot orthotic device with novel adhesive electrode for the treatment of foot drop.

ii. To provide a customized ankle foot orthotic device with novel adjustable strap for the treatment of foot drop.

iii. To provide a novel customized foot orthotic device for improving gait and rehabilitation.

iv. To provide a device that could reduce the pain as compared to conventional AFO while treating foot drop.

2. Literature Review

Prenton et al., [6] discloses that the people with multiple sclerosis (MS) have difficulty walking. According to the authors, gait impairment, including the reduced ankle dorsiflexion of foot drop, is one of the most common indicators of disability early in the course of this progressive auto-immune disease of the central nervous system, affecting approximately 75% of people with MS. Assistive technology, such as ankle–foot orthosis (AFO) and functional electrical stimulation (FES), increases the safety of walking and the speed of ambulation (even then, only about one half of patients remain ambulatory 15 years after disease onset). Assistive technology also reduces the risk of injury to the knee and ankle and reduces the effort of ambulation. Walbran et al., [7] discloses that “Cerebral Palsy (CP) is a non-progressive neurological disorder which develops in-utero or after birth. Current treatment for CP includes physical therapy and braces used to increase ambulation. Ankle–Foot Orthoses (AFOs) are lightweight plastic braces that secure the lower leg, ankle, and foot in a predetermined position, commonly used to aide dorsiflexion in CP patients. In another study [8] the common treatment, Functional Electrode Stimulation (FES), is administered by physical therapists in order to build muscle tone and improve dorsiflexion. According to the study, FES uses low energy electrical stimulation to excite either the common peroneal nerve or the tibialis anterior muscle, causing the patient to actively dorsiflex, increasing foot-ground clearance. Carolus et al., [9] discloses neuro-muscular disorders and injuries such as cerebral palsy and stroke often result in foot-drop which can result in a person having great difficulty walking. Ankle foot orthoses (AFOs) or splints have been prescribed for many years now to limit the range of motion of the ankle, provide the patients with support and assist with rehabilitation. However the majority of AFOs require a long, labour-intensive manufacturing process which results in unacceptable waiting times for children that are rapidly growing and patients with varying conditions. Deckers et al., [10] discloses AFO designs vary in size, shape, and functional characteristics depending on the desired clinical application. Passive Dynamic (PD) Response ankle–foot orthoses (PD-AFOs) constitute a design that seeks to improve walking ability for persons with various neuromuscular disorders by passively (like a spring) providing variable levels of support during the stance phase of gait. This study compared the mechanical damping of the CF-AFO to PD-AFOs manufactured by SLS using three different materials. The study showed that a SLS-based framework is ideally suited for this application.

3. Materials and Method

3.1. Materials

The present paper provides a customised ankle foot orthotic device for improving foot drop of a patient selected from strokes, multiple sclerosis, cerebral palsy patients and common peroneal nerve injury. The device of the present invention consist of:
1. Calf piece; 2. Calf strap; 3. Portable Muscle stimulator; 4. Stimulator suspension consisting of press button with nylon strap; 5. Adhesive electrode; 6. Electrical wires; 7. 2D hinge joint consisting of 4mm MS nut and bolt; 8. JBR outsole; 9. Foot piece; 10. Ankle strap; 11. Forefoot strap; 12. Ring; 13. Adjustable strap; 14. Press button; 15. Cold and Hot pack pouch; 16. Upward projection; & 17. Shank;

A customized AFO device that is applied to the ankle for modifying functional characteristics of neuro-muscular conditions. Characterized in the context that the adhesive strap being mounted on the rings so as to keep the plantar section of the foot piece in straight position and wherein the adhesive strap being made up by a combination of polyvinyl chloride, polypropylene and polyethylene wherein polyvinyl chloride, polypropylene and polyethylene is 1:1:2 by weight; wherein the cold and hot pack pouch being made up of 40.5%wt. water; 40.5% wt. ammonium nitrate, 4%wt. hydropropylmethyl cellulose and 15%wt. propylene glycol; and wherein the said electrode being made up of a hydrogel comprises of acrylic acid and N-vinylpyrrolidone.

3.2. Details of the Device

The presented device mainly consists of two sections: a Calf piece and a Foot piece which are articulately joined on each side of the ankle by two hinge joint of MS nuts and Bolts. The calf piece comprises a calf strap with an upper portion which may be wrapped around the patient’s calf and secured by a velcro strap. The strap is attached to one side of the greave while the other end is free and is designed to loop around the calf. Below the strap, there is a stimulator suspension which consists of press buttons in which portable muscle stimulator is mounted. The greave extends downward from the calf area to forward narrow shank below which the greave broadens at ankle area to match the contour of the ankle. The plantar section has a JBR (Johnson bros rubber) outsole and an upward project on which intimately wraps around heel & ankle areas of the patient. The hinge joints are mounted loosely so that a plantar section can rotate upward around the axis delineated by the two hinge. This movement of plantar section provides for dorsiflexion of foot during the swing phase of gait cycle. The downward movement of plantar section is stopped when the upper edge of the projection comes in contact with the on the inner side of greave thus, preventing the foot drop. The two sections and of the present device are made from thin-sheeted polypropylene material which are designed so as to counter the shape of the objects leg and foot. Ankle strap is looped around the ring ankle so as to fasten the strap tightly around the ankle. Forefoot strap which is looped around the forefoot so as to fasten the strap tightly around the forefoot. Adjustable straps is mounted on respective side by a ring for keeping plantar section in a stretched position.

Electrical muscle stimulator consist of two adhesive electrodes attached by electrical wire. Pouch which is the inner aspect of calf piece of AFO includes cold and hot pack. All the straps herein are embedded by press buttons. All straps are embedded by press buttons. The self-adhesive hydrogel electrodes according to present invention is prepared by the method as given by Malesevic et al., [11]. The impulses are generated by the device and are delivered through electrodes on the skin near to the muscles being stimulated. The electrodes are generally pads that adhere to the skin. The impulses mimic the action potential that comes from the central nervous system, causing the muscles to contract.

The self adjusted strap herein is used for stretching purposes in which specific muscle or tendon (or muscle group) is deliberately flexed or stretched in order to improve the muscle's felt elasticity and achieve comfortable muscle tone. The result is a feeling of increased muscle control, flexibility, and range of motion.

3.3 Experimental Study

The experimental trial as to evaluate the efficacy of the present device for foot drop was conducted in Krishna Institute of Physiotherapy, near Dhebewadi Road, Malkapur, Karad, Pin code-415110, Maharashtra, India. 10 patients whose average weight of 40-70 either gender, was selected for the following each groups as given:

Goup-I: strokes;
Goup-II: multiple sclerosis; 
Goup-III: cerebral palsy patients; & 
Goup-III: common peroneal nerve

EMS modes 
There were two EMS modes of option, S (synchronous) or A (alternate). Select a mode by pressing the mode control when a EMS mode is selected, the LCD shows EMS on the top. After a mode is selected, press SET control to enter next setting. The patient may adjust the setting only when it is flashing and then press the increment or decrement control to change the settings.

Ramp Time 
The ramp time controls the time of output current that increase from 0 to the setting level, and from the setting value to 0. When the ramp time was set, each contraction was ramped up and down in order that the signals come on and come off gradually and smoothly. The ramp time was adjustable from 1 to 8 seconds. The on-off range is adjustable from 2 seconds to 90 seconds.

10-meter walk test: 
The present device was evaluated by 10-meter walk test and the results were noted in metres/second. The individual was walked without assistance for 10 metres, with the time measured for the intermediate 6 metres to allow for acceleration and deceleration. Assistive devices may be used, but must be kept consistent and documented for each test. Count the start time when the toes pass the 2 metre mark and stop time when the toes pass the 8 metre mark. It can be tested at either preferred walking speed or maximum walking speed (ensure to document which was tested). This test was performed for each group of disease three times and calculated the average of the same.

4. Results 
The test results (Table 1-4), showed the superior effect of customized ankle foot orthotic device as compared to conventional AFO in view of both 10-meters walk test and the visual analogue scale for different diseases conditions.

| SN | Patients age | 10 meter walk test SPEED (metres/sec) | Visual analogue scale |
|----|--------------|--------------------------------------|-----------------------|
|    |              | Customized AFO device (Proposed)     | Conventional AFO°     | Conventional AFO° | Customized AFO device (Proposed) |
| 1  | 40           | 0.97                                 | 0.71                  | 8           | 2               |
| 2  | 45           | 0.99                                 | 0.68                  | 7           | 2               |
| 3  | 55           | 0.97                                 | 0.73                  | 9           | 1               |
| 4  | 60           | 0.99                                 | 0.65                  | 6           | 2               |
| 5  | 58           | 0.98                                 | 0.73                  | 6           | 1               |
| 6  | 59           | 0.99                                 | 0.69                  | 7           | 4               |
| 7  | 53           | 0.94                                 | 0.72                  | 8           | 4               |
| 8  | 54           | 0.98                                 | 0.76                  | 9           | 1               |
| 9  | 55           | 0.98                                 | 0.70                  | 8           | 3               |
| 10 | 45           | 0.92                                 | 0.68                  | 9           | 4               |
conventional AFO was prepared with the same components as in present device but without the adhesive electrode, the hot & cold pack unit and adjustable strap. Silicone electrode was used in the conventional AFO.

Table 2: Group II (multiple sclerosis)

| SN | Patients age | 10 meter walk test SPEED (metres/sec) | Visual analogue scale |
|----|--------------|--------------------------------------|----------------------|
|    |              | Customized AFO device (Proposed)     | Conventional AFO#    | Customized AFO device (Proposed) |
| 1  | 55           | 0.98                                 | 0.69                 | 9                     |
| 2  | 45           | 0.96                                 | 0.70                 | 6                     |
| 3  | 56           | 0.89                                 | 0.73                 | 7                     |
| 4  | 95           | 0.99                                 | 0.75                 | 8                     |
| 5  | 58           | 0.96                                 | 0.68                 | 9                     |
| 6  | 65           | 0.98                                 | 0.78                 | 6                     |
| 7  | 40           | 0.97                                 | 0.77                 | 5                     |
| 8  | 42           | 0.94                                 | 0.71                 | 8                     |
| 9  | 49           | 0.96                                 | 0.77                 | 7                     |
| 10 | 54           | 0.94                                 | 0.74                 | 8                     |

Table 3: Group III (cerebral palsy patients)

| SN | Patients age | 10 meter walk test SPEED (metres/sec) | Visual analogue scale |
|----|--------------|--------------------------------------|----------------------|
|    |              | Customized AFO device (Proposed)     | Conventional AFO#    | Customized AFO device (Proposed) |
| 1  | 14           | 0.85                                 | 0.65                 | 5                     |
| 2  | 15           | 0.89                                 | 0.68                 | 7                     |
| 3  | 25           | 0.90                                 | 0.70                 | 6                     |
| 4  | 21           | 0.87                                 | 0.68                 | 9                     |
| 5  | 11           | 0.90                                 | 0.69                 | 4                     |
| 6  | 25           | 0.91                                 | 0.65                 | 7                     |
| 7  | 18           | 0.92                                 | 0.66                 | 5                     |
| 8  | 14           | 0.85                                 | 0.68                 | 6                     |
# conventional AFO was prepared with the same components as in present device but without the adhesive electrode, the hot & cold pack unit and adjustable strap. Silicone electrode was used in the conventional AFO.

Table 4: Group IV (common peroneal nerve)

| SN | Patients age | 10 meter walk test SPEED (metres/sec) | Visual analogue scale |
|----|--------------|-------------------------------------|----------------------|
|    |              | Customized AFO device (Proposed)    | Conventional AFO#    | Conventional AFO#    | Customized AFO device (Proposed) |
| 1  | 25           | 1.02                                | 0.85                 | 7                    | 3                                |
| 2  | 18           | 1.05                                | 0.89                 | 8                    | 2                                |
| 3  | 42           | 1.50                                | 0.90                 | 9                    | 2                                |
| 4  | 35           | 0.99                                | 0.78                 | 6                    | 3                                |
| 5  | 28           | 1.23                                | 0.91                 | 8                    | 1                                |
| 6  | 45           | 1.7                                 | 0.86                 | 5                    | 2                                |
| 7  | 54           | 1.56                                | 0.87                 | 7                    | 3                                |
| 8  | 52           | 1.22                                | 0.83                 | 8                    | 2                                |
| 9  | 70           | 1.23                                | 0.92                 | 7                    | 1                                |
| 10 | 22           | 1.11                                | 0.89                 | 9                    | 2                                |

# conventional AFO was prepared with the same components as in present device but without the adhesive electrode, the hot & cold pack unit and adjustable strap. Silicone electrode was used in the conventional AFO.

5. Conclusion

The orthotic device of the present invention improves the gait and rehabilitation, in previously used orthosis there were not active dorsiflexion which is very important for gait training and rehabilitative purposes we just have to wear and do gait training, thus our device is doing dorsiflexion of ankle with the help of functional electrical stimulation through adhesive pads which is fitted on tibialis anterior muscle, that also gives positive feedback. The proposed customized ankle foot orthotic device increases the speed of a foot drop patient in treadmill as compared to conventional AFO.

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