The effect of a modified elastic band orthosis on gait and balance in stroke survivors

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Abstract

Introduction: Gait is crucial for independent living for stroke survivors and assistive devices have been developed to support gait performance. Ankle foot orthoses (AFOs) are commonly provided to stroke survivors to prevent foot drop during walking. However, previous studies have reported limitations of AFOs including them being too heavy, creating skin irritation, and being a stigma of disability. The purpose was to compare the gait and balance improvement between elastic band orthoses (EBOs) and AFOs.

Materials and Methods: The AFOs and EBOs were provided to 17 stroke survivors, and changes in gait and balance were assessed compared to barefoot (control). Gait spatiotemporal parameters were measured using the zebris-FDM-Rehawalk® system, and balance ability was evaluated using the timed up and go test (TUG). Satisfaction with the EBOs was determined using the Quebec user evaluation of satisfaction with assistive technology (QUEST2.0) questionnaire.

Results: The EBO showed significant differences in; gait speed, cadence, stride length, stride time, step length unaffected side, stance phase and swing phase on the affected side, and pre-swing on the unaffected side, and balance performance (TUG) ($p<0.05$) when compared to the AFO and control conditions. The participants were quite satisfied with the EBOs with QUEST2.0 scores greater than 4 out of 5.

Conclusions: EBOs could be provided to stroke survivors given their acceptability and properties to improve gait and balance. The EBO used in this study offered clinically important improvements in gait and balance when compare to AFO and control conditions, and could mitigate against some of the limitations reported in the use of AFOs in stroke survivors.

Key words: elastic band orthoses, ankle foot orthoses, assistive devices, gait, satisfaction.

1. Introduction

Stroke is a leading cause of death and disability worldwide. The prevalence of stroke in Thailand has been reported to be 1.88% in people aged 65 years rising to 2.7% in older individuals [1]. Stroke often leads to hemiparesis and assistive devices are often provided to improve activities of daily living. Independent walking is one of the rehabilitation goals for hemiparetic patients [2,3]. Spasticity is the most common impairment in motor function in stroke survivors affecting mobility, walking and transfer ability, and can induce an asymmetrical gait pattern and can contribute to compensatory movement patterns [2,4]. It has been reported that spasticity of ankle plantar flexors and invertors while walking often occurs, which can disturb an individual’s walking ability in both stance and swing phase of the gait cycle [5,6]. In stance phase, body weight is often distributed on the lateral border of the affected foot and increases stance time of the unaffected limb. In swing phase of the affected limb, patients will lean and shift weight to the unaffected limb resulting in an increased stance phase duration on the unaffected side. This could cause a loss of balance and lead to falls while walking independently [6,7].

Applying assistive technology (AT) to stroke survivors follows the Human, Activity, Assistive Technology (HAAT) model developed by Albert Cook [8,9], which highlights the importance of a needs evaluation from key stakeholders when considering the implementation of AT. Ankle foot orthoses (AFOs) are registered on the national assistive technology list for persons with disabilities in Thailand. The purpose of AFOs is to assist the patients in regaining walking ability, preventing foot-drop and the occurrence of toe clearance problems, promoting ankle stability during standing, and promoting heel strike [10-15]. These have been shown to increase ground reaction forces in individuals with plantar flexor weakness [16], however several studies have reported that AFOs might interfere with a patients’ gait performance due to their weight [10,17]. In long-term use these have been reported to reduce dorsiflexor muscle activation [18] and have also been shown to interfere with balance in stroke survivors [19]. In addition, when inquiring about the feeling while wearing AFOs, skin irritation and rashes over the contact areas have been reported [7,10,17,19-21].

Due to these existing limitations, the development of AT for stroke survivors to improve gait performance continues. Elastic band orthoses (EBOs) have been used to mitigate against some of the limitations of AFOs, which have been reported to improve balance and gait parameters in stroke survivors [13,22], however further studies are required to compare the effectiveness of EBOs with AFOs before being widely implemented within AT service delivery. EBOs have been presented in several patents from several countries [13,22,23]. However, to the authors' knowledge a comparison of EBO with AFO has not been reported. Therefore, the purpose of this study was to compare balance and gait performance in stroke survivors when using an EBO and AFO when compared to a control condition, and to determine user satisfaction with the EBO.

2. Methods

2.1. Participants

Participants diagnosed with stroke were recruited from the Prasat Neurological Institute, Bangkok, Thailand. All participants provided informed, written consent prior to enrollment in the study. The inclusion criteria were; diagnosis of hemiplegia due to hemorrhagic or ischemic stroke, more than 3 months post-stroke, age over 18 years, spastic ankle with plantar-flexion and inversion (Modified Ashworth Scale (MAS) 1-3), no shortening or contracture around the ankle, able to walk more than 10 meters independently with or without an assistive device, experience of using an AFO, and the ability to understand verbal instructions. Exclusion criteria were; stroke involving more than one hemisphere, recurrent stroke, Thai version of the Rowland Universal Dementia Assessment Scale (RUDAS) score of less than 24 out of 30, and pre-morbid or other musculoskeletal problems affecting gait performance. Ethics approval for this study was approved by the Human Research Ethics Committee (MU-CIRB 2018/144.1207) and (Ref. number 008/2562).

2.2. Sample size calculation

The sample size for this study was calculated using G*Power version 3.1 (G power, Germany)[24]. Time up and go (TUG) and spatiotemporal parameters were used to calculate sample size. Based on the data from a pilot study, the estimated sample to obtain a power of 90% with a five percent significance level was 17 participants.

2.3. Procedures

The researchers explained the protocol to participants and demonstrated walking on the Force Distribution Measurement/Win FDM device before taking consent. The participants were asked to walk barefoot (control condition) and whilst wearing an EBO and AFO (with shoes), the order of which were randomised. The barefoot condition aimed to investigate the spatiotemporal parameters without any support, and the AFO condition was used as a reference standard management to compare with the EBO. They were required to walk 10 meters at their most comfortable speed, and were allowed to use an additional walking aid if needed. Three trials under each condition were performed over a 3 meter walkway, and a 3 minute rest was allowed between trials and a 10 minute rest was allowed between conditions.

2.4 EBO and AFO interventions

The EBO consisted of an open toe non-slip sock with two straps (Figure 1a, b). The two different lengths of straps are attached on both sides of the sock. A long strap is placed on the medial side and goes across the top of the dorsum of the foot to the opposite side above the lateral malleolus and wraps around the lower leg above the gastrocnemius back to the medial side. The short strap on the lateral side goes across the top of the dorsum of the foot and wraps across the gastrocnemius back to the lateral side. Both straps are fixed with Velcro in front of the tibial tuberosity. The AFO was a non-hinged custom-made Polypropylene Posterior Leaf Spring (Polypropylene PLS), and was chosen and fitted by a qualified practitioner (physician, PT and Prosthetist) which considered the individual participants clinical needs (Figure 1c). The protocol and material used in the AFO production was similar for all participants.

2.5. Outcome measures

The TUG is a standard test for testing mobility and balance impairment. This test required participants to stand up, walk 3 meters, make a turn, walk back to the chair, and sit down. The time was recorded from when their buttocks lifted from the chair to when their buttocks touched the seat. During the turn the participants were required to turn toward the unaffected side.

Spatiotemporal gait parameters included; velocity, cadence, stride length, step length, stride time, step time, stance time, single support time, and double support time, which were recorded on the Zebris FDM Rehawalk® system. The walkway consists of an electronic mat embedded underneath a walkway consisting of 10,240 miniature force sensors, each approximately 0.85 × 0.85 cm, which recorded the foot placements and timings. The stride length and step length were normalized by participants' height.

The modified Ashworth scale (MAS) is the most widely used clinical scale used to measure muscle spasticity in the subacute and chronic phases post stroke. The spasticity according to the MAS (0 = no spasticity, 5 = rigidity), was assessed in the hip adductors, knee flexors and extensors, ankle plantar flexors and supinators. In addition, the Fugl-Meyer Motor Assessment-Lower Extremity (FMA-LE) was used to evaluate the motor function. FMA-LE consists of 17 items, with a maximum possible score of 34 points. Each item was answered using a 3-point ordinal scale (0 = cannot perform, 1 = can partially perform, 2 = can fully perform). In addition, the Rowland Universal Dementia Assessment Scale (RUDAS)-Thai version was used to screen cognitive performance. The RUDAS score lower or equal to 23 represents a cognitive function impairment. All assessments were completed by trained registered physical therapists.

The Quebec user evaluation of satisfaction with assistive technology version 2.0 (QUEST 2.0) is a 12-item outcome measure that assesses user satisfaction with the device (8 items), services (4 items), and open-ended questions. The 8 device items and open-ended questions were collated to assess user satisfaction of the EBO.

2.6. Data analysis

The general characteristics of participants were analyzed using descriptive statistics. Kolmogrov Smimov tests were used to identify the distribution of the data and all data were found to be not normally distributed. Friedman tests were performed to determine differences between the conditions for the affected and unaffected sides separately. Where significant differences were seen post hoc Wilcoxon-signed rank test were performed to determine differences between individual conditions for the gait and balance outcome measures. All data were analyzed using SPSS (IBM, USA), and the alpha level was set at 0.05.

3. Results

Seventeen individuals (11 males and 6 females) with hemiplegia were recruited. The mean age was 50.82 ± 13.54 years with a mean body mass index of 22.86 ± 2.70 kg/m^2. The participants characteristics are presented in Table 1.

3.1. Gait and balance measures

Friedman tests revealed significant differences between the three conditions for; stride length (p=0.016), stride time (p=0.006), cadence (p=0.005), velocity (p=0.001), percentage stance phase on the affected side (p=0.025), percentage swing phase on the affected side (p=0.025), step length on the unaffected side (p=0.029) and percentage pre-swing phase on the unaffected side (p=0.025). In addition, the TUG test also showed significant differences between the three conditions (p=0.001).

Post hoc Wilcoxon Signed Rank test showed differences between the EBO and the control condition with the EBO showing an increase in stride length (p=0.009), percentage swing phase on the affected side (p=0.003), and step length on the unaffected side (p=0.035). Moreover, the EBO showed a decrease in the percentage of stance phase on the affected side (p=0.01), percentage of pre-swing phase on the unaffected side (p=0.035), and TUG test (p=0.008). Significant differences were also seen between the EBO and AFO conditions with the EBO showing a greater stride length (p=0.008), cadence (p=0.004), velocity (p=0.001), and step length on the unaffected side (p=0.031), with a shorter stride time (p=0.009) and TUG test time (p=0.001). In addition, the AFO increased velocity (p=0.044) when compare to the control condition. The AFO showed higher TUG test time when compare to control condition, but it was not significant difference (Table 3, Figure 2-3).

3.2. User Evaluation of Satisfaction

The QUEST 2.0 and open-ended questions showed that participants were most satisfied with the weight of the EBO (Median=5, IQR=0) and were least satisfied with the durability (Median=3, IQR=1) (Table 2). The open ended questions of QUEST showed positive comments from participants about the EBO associated with the weight and ability to walk freely, better than the AFO (100%). The participants reported that they wanted to use the EBO at home in their daily activities (82.4%). However, 17.6% reported they did not want to use the device with the most common reasons being they needed more time to practice with the EBO, with some participants not wanting to use any assistive device. Additional comments included that the EBO felt like wearing a pair of socks, which was comfortable and supported firmly at the ankle, and made the participants feel more confident during walking (100%). They also perceived that the EBO aided their walking pattern and corrected their posture and helped their speed (100%). Moreover, they reported that their ankle and toe twitch during walking were decreased (58.8%).

4. Discussion

Assistive technology for stroke survivors has been developed for decades. Several studies have demonstrated that ankle supports can alter gait and balance performance in this population [7,10-15,17,20,22,23]. Several types of ankle support are available which include ankle foot orthosis (AFO), which are prescribed to stroke survivors to support their ambulation. However, the AFO still has some limitations, especially limiting ankle movement during walking [12,17,19,21]. The purpose of this study was to investigate the effect of an elastic band orthosis on gait and balance performance in stroke survivors and to provide a comparison with AFOs.

4.1 Gait and balance performance

Gait and balance performance was assessed through spatiotemporal gait parameters and the TUG test. Significant differences were found in velocity, cadence, stride length, stride time, stance phase and swing phase on the affected side, and pre-swing and step length on the unaffected side, and the TUG test when using the EBO. These findings are in line with previous studies whereby step length on the unaffected side was improved after applying both rigid and elastic ankle supports [14,22,25]. However, the EBO significantly improved spatiotemporal gait parameters when compared with the AFO. This implies that the EBO encourages weight bearing and gait performance during stance phase on the affected side, and longer step lengths on the unaffected side. When comparing the two devices the AFO limits the amount of ankle dorsiflexion which affected reaching and gait performance [15,17,26]. Particularly during stance, limited ankle dorsiflexion in the affected side could lead to a shorter step length [27], and stride length in the AFO when compared to the control condition and EBO. Whereas the EBO offers little restriction of dorsiflexion as this is made from elasticated fabric.

The EBO subtly altered the proportions of stance phase and swing phase of the affected side moving these closer to the normal stance and swing proportions (60:40) when compared to the control and AFO conditions. The decrease of pre-swing phase on the unaffected side while walking using the EBO indicated that the transition phase between stance and swing on the unaffected side was improved. This phenomenon might be related to improved stability of the affected side during the stance phase, and lead the unaffected side to become more efficient during propulsion [10,13,14,23]. These affects are associated with force from the elastic bands within the EBO which provide some supportive properties for the ankle joint during single limb loading in stance phase on the affected side, and might lead to a longer step length of the unaffected side. Collectively this led to the improvement in stride time, cadence, velocity and TUG test time in this sample of stroke survivors. However, the elastic properties and the optimum force needed for the best function needs to be further explored.

4.2. User Evaluation of Satisfaction

The QUEST 2.0 questionnaire was used to evaluate satisfaction with the EBO. The questionnaire was selected as it has previously been presented to be a valid measure of satisfaction with assistive devices [28]. Overall, patients were quite satisfied with the EBO (Median=4, IQR=1). All participants supported that the EBO could be used to improve balance during walking. It encouraged participants to walk confidently, and their comments seemed to relate to the findings from the gait and balance performance measures. Compared to the control condition, the EBO was reported to support the affected ankle in dorsiflexion with eversion, which promoted patients’ ability to clear their toe from the floor and the participants reported that the EBO felt lighter than the AFO. It is noteworthy that polypropylene development and hybrid AFOs made of polypropylene and fabric have been explore to facilitate the gait in stroke survivors [28-30]. The lighter weight orthoses showed a higher level of satisfaction which supports the current findings from the EBO. While the majority of items showed users were quite satisfied with the EBO (7 out of 8 items), the durability of the EBO presented as more or less satisfied (1 out of 8 items). Following the concept of the HAAT (Human, Activity, Assistive Technology) model evaluated by QUEST 2.0, the EBO improved the gait and balance performance for stroke survivors during walking [8,9]. Participants (82.4%) agreed that the EBO was suitable for their home environment and wanted to use the EBO in their daily living. The EBO seems to offer better results than the AFO when considering both the gait and balance performance and comments from this sample of stroke survivors. A comparison of the satisfaction when wearing AFOs and EBOs using the QUEST 2.0 might be considered in further investigations.

It has been presented that the Fugl-Meyer score of lower extremity function cut-off score for high level of mobility function in chronic stroke survivors is 21 out of 35[31]. Using this score all participants in this current study were deemed to have a high level of mobility function (Table 1). Further investigation in individuals with different levels of function to further understand the generalizability of these results is recommended.

5. Conclusion

The EBO seems to improve TUG, gait velocity, cadence, stride length, stride time, stance phase and swing phase on the affected side, and pre-swing and step length on the unaffected side over both the AFO and control conditions, which are reflected by the user evaluations of satisfaction. Therefore, the EBO could be used in clinical and community settings, and could mitigate against some of the limitations reported in the use of AFOs in stroke survivors.

Figure 1 The Elastic Band Orthosis (EBO) (The A band contributes the inversion and the B band contributes the eversion) (a-b) and Polypropylene Posterior Leaf Spring (Polypropylene PLS) (c)

Figure 2 Presented the median (IQR) among three groups (Control, AFO and EBO). The post hoc Wilcoxon Signed rank test identified the significant difference between pairs.

Figure 3 Presented the median (IQR) of stride time (sec) and velocity (km/hr.) among three groups (Control, AFO and EBO). The post hoc Wilcoxon Signed rank test identified the significant difference between pairs. (* $P<0.05$, ** $P<0.005$)

Table 1 Present the specific conditions and lower limb Modified Ashworth Scale (MAS)

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Table 3 Present the spatiotemporal parameters and TUG among 3 conditions (Control, AFO and EBO)

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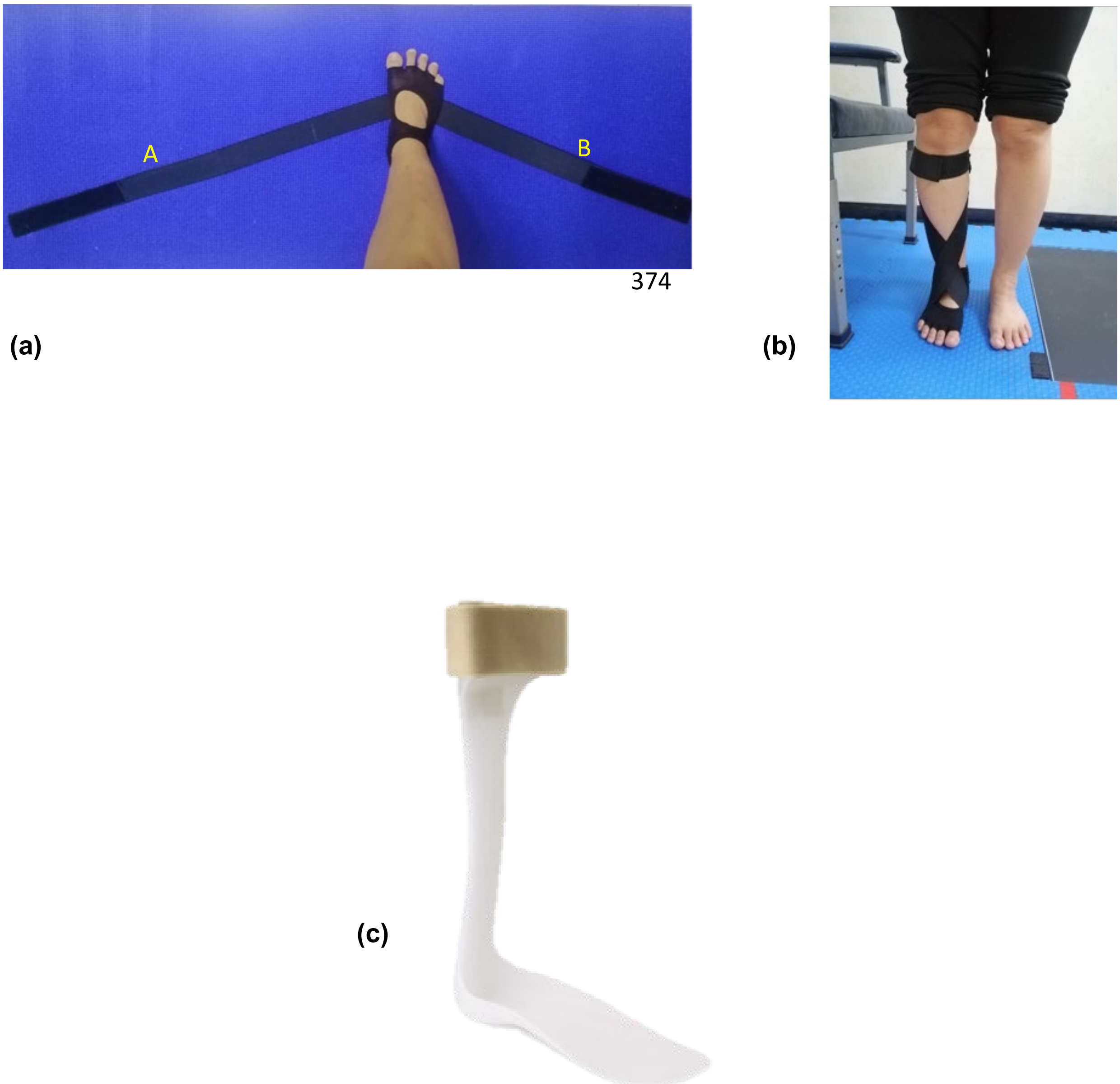

(a) (b)

(c)

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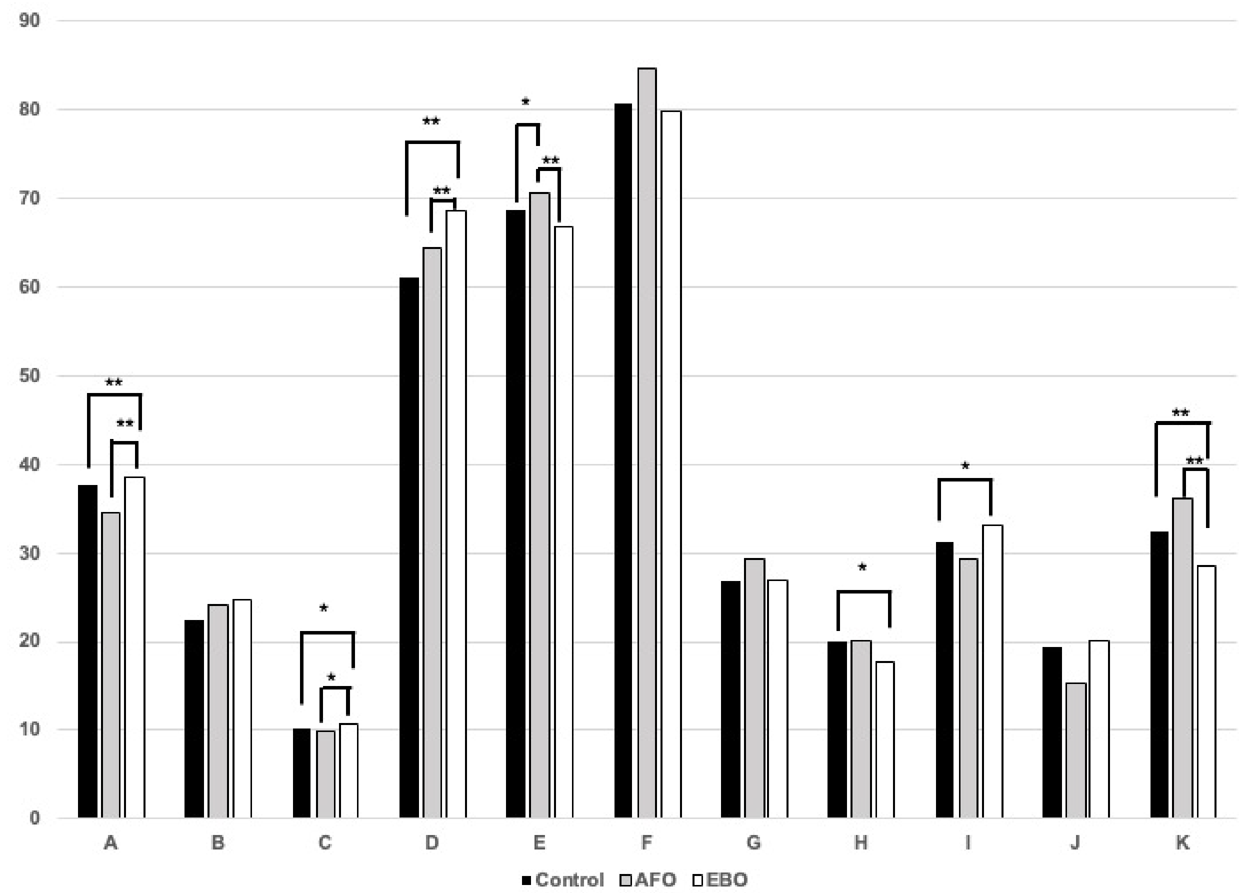

Figure 2 Presented the median (IQR) among three groups (Control, AFO and EBO). The post hoc Wilcoxon Signed rank test identified the significant difference between pairs.

(* P<0.05, ** P<0.005, A= Stride length (%), B= Step length affected side (%), C= Step length unaffected side (%), D= Cadence (step), E= Stance phase affected side (% gait cycle), F= Stance phase unaffected side (% gait cycle), G= Pre-swing phase affected side (%), H= Pre-swing phase unaffected side (%), I= Swing phase affected side (%), J= Swing phase unaffected side (%), and K= Time up and go (TUG) (seconds))

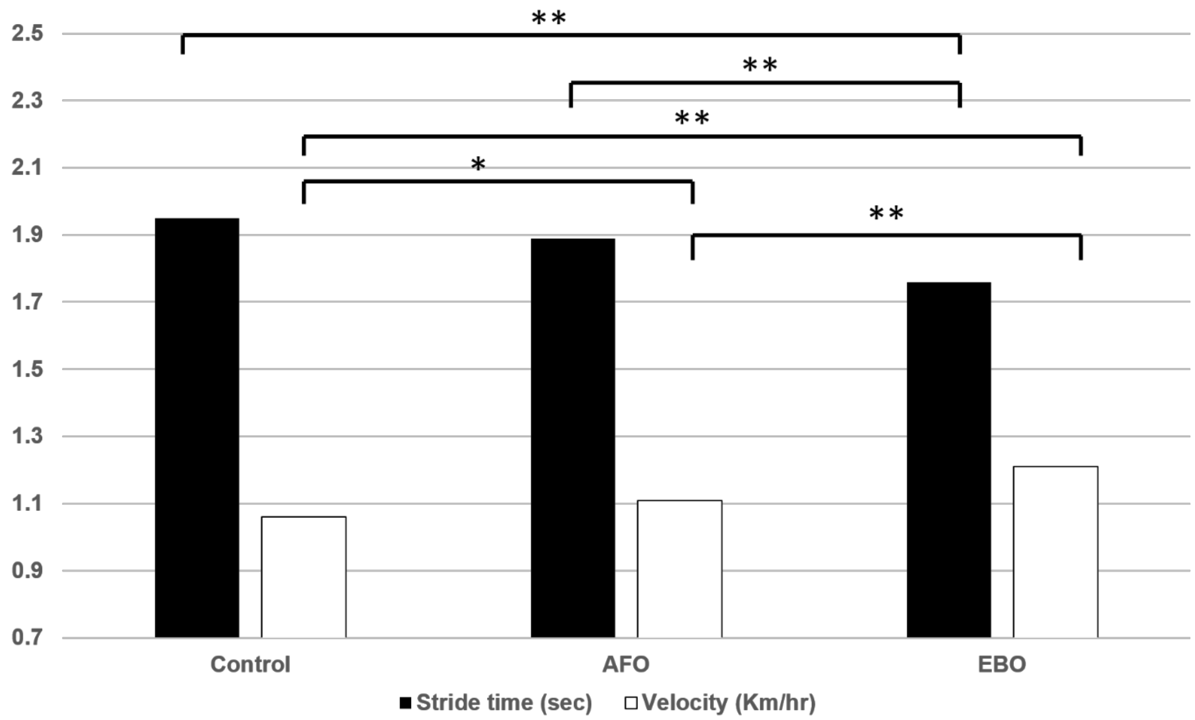

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Table 1 Present the specific conditions and lower limb Modified Ashworth Scale (MAS)

Conditions	Mean ± SD	Number	Percent (%)
Diagnosis			
Ischemic stroke		15	88.20
Hemorrhagic stroke		2	11.80
Duration of onset (months)	10.65±16.63		
Affected side			
Left		9	52.90
Right		8	47.10
Modified Ashworth Scale (MAS):			
Ankle planta flexor and supinator		7	41.20
Spasticity Level 1		10	58.80
Spasticity Level 2			
Fugl-Meyer Motor Assessment (FMA) Lower Extremity) (total = 34)	25.00 ± 3.20 (Min = 18 - Max = 29)		
Rowland Universal Dementia Assessment Scale (RUDAS, total 30)	29.26 ± 1.28 (Min = 25 – Max = 30)		

Table 2 Present the Quebec User Evaluation of Satisfaction with assistive Technology version 2.0 (QUEST-2.0), Assistive device section, from participants after used EBO

QUEST (Version-2.0) Assistive device	Score EBO from participants	
	Median	IQR
1. the dimensions (size, height, length, width) of your assistive device?	5	0.5
2. the weight of your assistive device?	5	0
3. the ease in adjusting (fixing, fastening) the parts of your assistive device?	4	1.5
4. how safe and secure your assistive device is?	4	1
5. the durability (endurance, resistance to wear) of your assistive device?	3	1
6. how easy it is to use your assistive device?	4	1
7. how comfortable your assistive device is?	4	1
8. how effective your assistive device is (the degree to which your device meets your needs)?	4	1
Overall score	4	1

Table 3 Present the spatiotemporal parameters and TUG among 3 conditions (Control, AFO and EBO)

Spatiotemporal gait parameters	Median (IQR)			p-value[a]
	Control	AFO	EBO	
Velocity (km/h)	1.06 (0.99)	1.11 (0.82)	1.21 (0.98)	0.001**
Stride length (%)	37.73 (17.70)	34.64 (15.14)	38.50 (17.75)	0.016*
Step length (%) -Affected side -Unaffected side	 22.33 (6.84) 10.27 (11.08)	 24.12 (6.97) 9.92 (15.90)	 24.64 (11.38) 10.69 (15.27)	 0.51 0.029*
Cadence (step/minute)	61.17 (33.20)	64.37 (24.13)	68.62 (27.00)	0.005*
Stride time (sec)	1.95 (1.05)	1.89 (0.78)	1.76 (0.79)	0.006*
Stance phase (% gait cycle) -Affected side -Unaffected side	 68.70 (11.75) 80.68 (12.56)	 70.66 (12.29) 84.66 (11.62)	 66.77 (11.83) 79.88 (11.35)	 0.025* 0.33
Pre-swing phase (%) -Affected side -Unaffected side	 26.81 (15.54) 20.11 (7.15)	 29.34 (13.79) 20.12 (10.51)	 26.90 (17.24) 17.8 (7.31)	 0.66 0.025*
Swing phase (% gait cycle) -Affected side -Unaffected side	 31.30 (11.75) 19.32 (12.56)	 29.34 (12.30) 15.34 (11.62)	 33.23 (11.82) 20.12 (11.31)	 0.025* 0.33
TUG score (seconds)	32.40 (24.23)	36.05 (22.26)	28.60 (23.81)	0.001**

[a] Friedman test, IQR = Interquartile Range, * P<0.05, ** P<0.005