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Effects of Customized Biomechanical Footwear on Gait and Balance in Individuals with Polio: A Randomized Controlled Trial

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Abstract

Background

Evidence suggests that the factors behind the increased risk of falls among polio survivors are mainly categorized into intrinsic and extrinsic domains. The intrinsic category involves factors like muscle weaknesses, fear of falls and self-reported balance problem. In contrast, extrinsic factors include poor environmental circumstances and ambulatory issues that cause reduced ability to adapt to walking conditions in polio patients. Therefore, the present study aimed to investigate biomechanical footwear's effects on gait and balance in individuals with polio.

Methods

A total of 30 participants were randomly divided into two groups of 15 each. The experimental group received customized shoe footwear with features such as medial arch support, metatarsal pad, rear foot control, fibreglass lateral counter, and a rocker sole. The control group did not receive specialized footwear.

Results

The intervention group showed significant improvements in several gait parameters compared to the control group, including step length ($p=0.008$), stride length ($p=<0.001$), step width ($p=0.002$), cadence ($p<0.001$) and speed ($p=0.0009$). The intervention group also showed significant improvements in Berg Balance Scale scores ($p=0.07$) compared to the control group.

Conclusion

Biomechanical footwear with medial arch support, metatarsal pad, and rear foot control can improve gait and balance in individuals with polio.

Keywords

Disability, Gait, Foot Orthosis, Poliovirus

Introduction

Enterovirus infection is the most common form of viral neuropathy causing acute flaccid paralysis (AFP) among children ≤15 years of age[1-2]. These viruses include Coxsackievirus, Enterovirus 68 and 71, Echovirus and Poliovirus[3]. The pathogen belongs to the Enteroviruses genera within the family of Picornaviridae and has a single-stranded Ribonucleic acid (RNA) genome comprising 60 subunits in each capsid[4]. AFP is a clinical syndrome characterized by a limb's sudden onset of weakness that progresses to maximum severity within days or weeks[5]. Etiological factors behind AFP are multiple, including both infections and non-infectious causes[6]. Infections mainly occur due to viruses and bacteria, whereas non-infectious causes may include neurological lesions, trauma, toxic exposure, cancer, and other factors[7]. Evidence suggests that more than 50% of AFP is caused by Guillian-Barree Syndrome (GBS), an autoimmune disease with multiple etiology[8]. In addition, AFP is a characteristic feature of paralytic poliomyelitis, with a known etiology that is the Poliovirus. Therefore, the World Health Organization initiated the Global Polio Eradication Program in 1988 to eradicate and contain all wild, vaccine-induced and Sabin Polioviruses globally[9]. Pakistan and Afghanistan are the only countries where the spread of endemic wild poliovirus has never stopped. The government of Pakistan has spent nearly US$387 million and US$121 million on the GPEI through loans provided by Islamic Development Bank and Japan International Cooperating Agency, respectively, and US$58 million through assistance provided by other national governments[10]. According to the data from the Pakistan Polio Eradication program website, 20 poliovirus cases were detected in 2022. In contrast, only one case was reported in 2021, the number of reported cases in 2020 was 84, and in 2019 the number of reported cases was 14711. The incidence of polio cases is not the only focus of concern for the government, society, families and patients. However, another essential aspect of polio that requires attention is a post-polio syndrome, which progresses slowly over decades and gives rise to many complications like a walking limitation, participation restriction and poor quality of life[12]. Besides these complications, another critical factor that affects a patient's quality of life is the increased risk of falls, which intensifies with the increase in age[13]. According to the study, 55% to 84% of polio patients encounter one fall annually, which is considerably high compared to older adults aged ≥65 years with no polio, whose annual fall encounter is 28% to 33%[13]. Evidence suggests that the factors behind the increased risk of falls among polio survivors are mainly categorized into intrinsic and extrinsic domains. The intrinsic category involves muscle weaknesses, fear of falls and self-reported balance problems. In contrast, extrinsic factors include poor environmental circumstances and ambulatory issues that cause reduced ability to adapt to a walking condition in polio patients[14]. Therefore, the present study aimed to investigate biomechanical footwear's effects on gait and balance in individuals with polio.

Methodology

Study Setting

A study was conducted in a rehabilitation department under the authority of community-based polio rehabilitation centres in Karachi, Pakistan.

Study Design

A randomized controlled trial was conducted, and randomization was performed based on a simple random sampling method.

Sample Size

The study was performed on a sample size of n=30 participants previously diagnosed with polio and unilateral or bilateral residual lower limb weakness.

Intervention

A total of n=30 participants were recruited and randomly divided into two groups. Each group contains n=15 participants. The experimental group was given customized, in-depth shoe footwear that comprised medial arch support, metatarsal pad and rear foot control. Besides that, a fibreglass lateral counter was also added to control a varus heel, and a rocker sole was added to release pressure from the metatarsal head. The participants in the control group were only provided in-depth shoes of 1/4 to 3/8 inch depth, more depth than regular shoes with no modification like heel wedge, lateral flare and rocker sole. Participants from both groups were provided physical therapy services to improve lower limb strength and parallel bar walking to improve GAIT for 12 weeks, five days per week, to prevent muscular weaknesses and improve gait patterns. Each session was comprised of 50-minutes duration.

Outcome Measure

The analysis was performed twice in both groups. In the experimental group, the first readings were taken on the day first when the participant was provided with customized shoe wear before physical therapy rehabilitation and the second after the completion of 12 weeks of training on the given footwear. In the control group, in-depth shoes were provided with no modification, and readings were taken on two similar occasions, as mentioned for the experimental group. Readings were taken on the following mentioned tools.

Gait Parameters

Gait parameters, including step length, stride length, step width, cadence and speed, were assessed using an active-graph accelerometer and a video recorder[15].

Balance

Functional balance was assessed using a Berg Balance Scale (BBS) to quantify individual balancing abilities. The scale comprises 14 items, each with 5 points ranging from 0 to 4 in ordinal form, with 0 indicating no function and 4 suggesting the highest level of functional balance. The test requires approximately minutes to complete[16].

Data Analysis

The analysis of data was performed on SPSS version 23. For demographic variables, frequency and percentage charts were formulated. Inferential statistics were analyzed using a parametric test at a 95% Confidence Interval. Paired t-test was run within the group analysis, and an independent t-test was applied between the group analyses. The level of significance was determined at cut off value of $p<0.05$

Ethical Considerations

All participants enrolled in the study were informed regarding the purpose of the study. Written consent was taken, and all the information from the participants was kept confidential. The participants were given complete autonomy to withdraw from the study at any time of trial. Ethical approval for conducting the survey was taken from Al-Rahim Medical and Rehabilitation Center, Karachi (IRB#ALR/MRC-021/2/22).

Results

The study was based on n=30 participants equally divided into Group A (n=15) and Group B (n=15). The demographic description of the participants revealed that the mean age of the participants was 48.23±2.4 years. The participants in Group A were in a mean age of 48.56±2.42 years, and participants in Group B were in a mean age of 48.13±2.4 years. The percentage of the male and female population in the study was 56.6% and 43.33%, respectively. A description of the demographic characteristics of the participants was provided in Table-1.

Table-1 Demographic characteristics of participants

Variables	**Total Number of Participants**	**Age**
Group A	15(50%)	48.56±2.42
Group B	15(50%)	48.13±2.4
Total	30(100%)	48.23±2.4
Frequency and percentage of male and female population		
Variables	Male (%)	Female
Group A	8(44.44%)	7(53.8%)
Group B	9(52.9%)	6(46.15%)
Total	17(56.6%)	13(43.33%)

n (%)
Mean±S.D.

Further, to determine the effects of customized footwear on gait and balance at baseline and week 12, paired t-test was applied that suggested a significant mean difference ($p<0.005$) in the parameters of the gait and BBS in both the groups except for speed variable in Group B where the mean difference was found to be non-significant ($p=0.19$) (Table-2).

Table-2 Paired t-test to determine effect of customized footwear on parameters of gait and balance					
Variables	**Baseline**	**Week 12**	**T Stat**	**t critical (two-tail)**	**p-value**
Parameters of Gait (Group A)					
Step Length (cm)	55.6±2.72	62.20±2.27	-6.94	2.14	<0.001
Stride Length (cm)	109.73±7.37	125.4±3.68	-8.99		
Step Width (cm)	8.17±1.02	5.87±0.72	5.98		
Cadence (steps/min)	87.02±33.35	115.67±4.15	-3.25		
Speed (m/sec)	0.87±0.23	1.25±0.17	-5.92		
Balance					
Berg Balance Scale	30.4±5.47	42.07±5.2	-9.49	2.14	<0.001
Parameters of Gait (Group B)					
Step Length (cm)	55.2±2.62	58.53±3.04	-3.42	2.14	0.004
Stride Length (cm)	109.07±7.27	117.33±3.01	-5.15		0.0001
Step Width (cm)	8.01±0.76	6.83±0.84	3.59		0.002
Cadence (steps/min)	90.13±5.125	100.53±6.59	-5.18		0.001
Speed (m/sec)	0.94±0.2	1.04±0.13	-1.37		0.19

Balance					
Berg Balance Scale	29.73±4.77	38.2±2.85	-5.34	2.14	0.001

Mean±S.D.

To determine the effectiveness of customized footwear independent t-test was applied, and the analyses of the findings revealed that customized footwear turned out to be significantly effective (p<0.005) in improving gait and balance parameters compared to non-customized footwear. Participants enrolled in Group A and trained on customized footwear had significantly improved in improving step length, stride length, step width, cadence, speed and balance (Table-3).

Table-3 Independent t-test to determine comparison between the two groups

Variables		**Week 12**	**T Stat**	**t critical**	**p-value**
Step length	**Group A**	62.2±2.27	3.73	2.04	0.008
	Group B	58.53±3.04			
Stride length	**Group A**	125.4±3.68	6.56		<0.001
	Group B	117.33±3.01			
Step Width	**Group A**	5.86±0.72	-3.32		0.002
	Group B	6.82±0.84			
Cadence	**Group A**	115.66±4.15	7.51		<0.001
	Group B	100.53±6.59			
Speed	**Group A**	1.24±0.17	3.69		0.0009
	Group B	1.03±0.13			
Balance	**Group A**	42.06±5.2	2.52		0.017

	Group B	38.2±2.85			

Mean±S.D.

Discussion

The analysis of the current study's findings revealed that customized footwear effectively improved gait and functional balance among poliomyelitis patients. In a study that aimed to determine the Health-Related Quality Of Life (HRQoL) and physical fitness among polio survivors, the authors concluded that both HRQoL and levels of physical fitness were compromised among polio survivors. In addition to that, patients were also found at increased risk of falls and lack of mobility[17]. In another study conducted to identify the influence of walking limitations on daily life among patients with the late effect of polio (LEoP), the authors concluded that limited walking abilities among LEoP severely affect everyday activities indoors and outdoors. To increase safety among LEoP patients, strategies such as using walking aids and orthotic devices, walking carefully, and avoiding risky activities can limit the risk of falls and prevent fall-related injuries[18]. In a study that was conducted to determine the effects of flexible-ankle foot orthosis on balance and walking ability in a person with LEoP, it was found that Ankle Foot Orthosis (AFO) had significantly improved ($p<0.05$) gait speed, outdoor walking and reduced perceived exertion. However, the study found no change in dynamic balance and increased walking safety. In addition, the study concluded that although AFO marginally improved walking ability, it can be a valuable method to enhance daily function[19]. According to the authors of the orthotic management of polio and post-polio syndrome, optimization in cardiorespiratory function and proper orthotic management can be effective methods in managing post-polio syndrome. Besides that, patient treatment must be based on an individualized approach based on customized modification as per the functional need of patients to get optimal benefit from the treatment option[20].

Although the findings of our study supported the concept of providing customized footwear in improving gait and balance among poliomyelitis patients yet we believed that there were certain limitations like small sample size, small duration of intervention and lack of follow-up visits preferably after six months or year to determine residual effects that need to be addressed to provide further concrete evidence in future regarding the impact of customized biomechanical footwear on gait and balance in Individuals with Polio.

Conclusion

The study has concluded that customized biomechanical footwear significantly improves gait and functional balance among polio patients. The findings revealed that all gait parameters, step length, stride length, width, cadence and speed, are significantly ($p<0.005$) better among patients to whom customized biomechanical footwear is given. Besides that, balance has also been found to improve substantially ($p<0.005$) after 12 weeks of training.

Authors Contribution

Irshad A: Conception, design and data acquisition.

Khan H: Design and data acquisition.

Latif D: Drafting and data analysis.

Bugti M: Data analysis and critical revision.

Khan RR: Revising the draft.

Bugti MK: Final approval.

Declaration of Interest

None.

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