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Research article

Additive manufacturing of specific ankle-foot orthoses for persons after stroke: A preliminary study based on gait analysis data

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Abstract: The aim of present study is to investigate the feasibility of patient-specific ankle-foot orthoses fabricated using additive manufacturing (AM) techniques. Then, clinical performance of the AFOs manufactured using material PA12 was evaluated in stroke survivors based on gait analysis data. The ankle and foot were scanned by EinScan—Pro 3D scanner. The software Geomagic Studio was used for modifying the AFO model. After processing the original AFO model into the final required model, material PA12 were used to fabricate the AFOs by Multi Jet Fusion (MJF) technique. Finally, gait analysis of 12 stroke patients was conducted to compare the effects with and without AFO. It took 2 hours from processing the initial AFO model to the completion of final model, and the printing time was 8 hours. The printing thickness of the AFO was 1.2 mm. With respect to the temporal-spatial parameters, the velocity and stride length in the gait with AFO increased significantly as compared to the gait without AFO ($P = 0.001$, $P = 0.002$). The cadence increased, double limb support phase decreased, and the step length difference decreased in the gait with AFO; however, the difference was not statistically significant ($P = 0.117$, $P = 0.075$, $P = 0.051$).This study confirmed the feasibility of patient-specific AFO fabricated by AM techniques, and demonstrated the process of modifying AFO models successfully. The specific ankle-foot orthoses fabricated by

material PA12 have a significant effect on the improvement of velocity and stride length in people with stroke.

Keywords: additive manufacturing; 3D printing; ankle-foot orthosis; stroke; printing material; gait analysis

1. Introduction

Patients with stroke often lose control and strength in their lower limbs, which impairs their mobility. Ankle-foot orthosis (AFO) could supports and aligns the ankle and foot and suppress the spastic and overpowering muscles, assist weak and paralyzed muscles [1]. Therefore, AFO is commonly prescribed to assist people with stroke for facilitating their ankle-foot function and increasing the walking speed and efficiency [2].

Traditionally, the approach to the design and fabrication of an AFO starts with wrapping the foot and lower limb in the glass fiber bandages and plaster in order to capture its size and geometry [3]. And then the prosthetist palpates for the pressure points at the bony prominences during the wrapping process, and marks down their locations. Finally, the cast of the residual part is removed and the plaster or fiberglass cast is discarded and destroyed after the plaster is set. Therefore, fabricating a custom-fit orthosis is time-consuming and very laborious. In addition, the process is also wasteful of materials, as the plaster molds and other excess fabrication materials are discarded during the fabrication process. The traditional AFO is often bulky and geometrically deficient and prefabricated orthotic devices lack individualized comfort and function.

Additive manufacturing (AM), also known as three-dimensional printing (3D printing), allow the production of new orthosis that is personalized with respect to the fit and shape [4–10]. The concept of using AM for the fabrication of AFO was first introduced by Milusheva and colleagues in 20055. Recently, some studies conducted in laboratory and research institute demonstrated the feasibility of AFO fabrication using AM techniques with different materials and techniques [4,11–15]. For example, the gait study on one subject showed equivalent walking performance of AFOs made by stereolithography (SLA) in comparison with conventional AFO [13]. Creylman et al. tested conventional polypropylene and selective laser sintering (SLS) AFOs on eight subjects with unilateral drop foot gait, evaluated gait performance and concluded that SLS AFOs had at least equivalent performances as conventional AFOs [15]. However, AM of AFO is inaccessible to many patients due to lack in AFO model design method, unsuitable printing material, and the high cost of acquisition [4,8], see review of Chen and colleagues [16]. The clinical evaluation of gait performance with or without AFO from AM technology for stroke survivors is still limited.

Therefore, the present study aimed to investigate the feasibility of patient-specific ankle-foot orthoses fabricated using AM techniques, and to demonstrate the process of modifying geometric AFO model. Then appropriate printing materials were applied and gait analysis of wearing the AFO was evaluated in stroke survivors with a hemiplegic gait at clinical settings.

2. Methods

2.1. Subjects

Patients were recruited in the study if they presented: (1) first onset of stroke, with unilateral paralysis; (2) completely affected posterior limb of an internal capsule (destructed corticospinal tract); (3) muscle strength at the proximal end of the paralyzed lower limb ≥level 3, and incapability to perform ankle dorsiflexion. Patients were excluded from the study if they: (1) suffered from severe pain in the lower limbs; (2) had serious cognitive or psychological barriers; (3) suffered from severe spasm in the lower limbs [lower limb spasticity >3 on the Modified Ashworth Scale (MAS)]. Between April 2014 and December 2018, a total of 12 stroke patients, admitted to the Department of Rehabilitation Medicine, Foshan No.1 People's Hospital, was selected (8 males and 4 females, aged 55.8 ± 9.2 years). The cohort consisted of 6 cases of cerebral hemorrhage and 6 of cerebral infarction (Table 1). All patients completed an intensive rehabilitation program and required the AFOs to support the ankle-foot function. Written consents were obtained from the participants before the experiment. This study was approved by the Research Ethics Board of the First People's Hospital of Foshan (L [2015] no.9), China.

Table1. Participant stroke information and demographics.

Patient	Gender	Age(year)	Height(cm)	Weight(kg)	Stroke type	Time after stroke(weeks)	Paretic leg
1	M	49	175	72	Ichemic	53	R
2	F	42	162	70	Hemorrhage	16	L
3	F	54	161	52	Hemorrhage	44	L
4	M	65	167	61	Ichemic	24	R
5	M	49	179	86	Ichemic	8	L
6	F	68	160	60	Ichemic	7	L
7	M	49	165	66	Ichemic	12	R
8	M	43	162	80	Hemorrhage	48	L
9	M	64	170	75	Hemorrhage	32	L
10	M	63	176	75	Ichemic	20	L
11	M	60	176	78	Hemorrhage	32	R
12	F	64	161	56	Hemorrhage	6	L

2.2. Procedures of additive manufacturing of AFO

The advantages of AM techniques include shorter lead times, mass customization, reduced parts count, more complex shapes, less material waste, and lower life-cycle energy use [4,17]. Several barriers need to be overcome include: AFO model design, printing material, and the high cost of acquisition [3,4,8,9,13]. The design and AM procedure were divided into four steps as follows: 1) Scanning of the ankle-foot joint using the 3D scanner (EinScan—Pro, SHINING 3D, China) to generate the initial design of the AFO; 2) Modifying the initial AFO model using the software Geomagic Studio (Geomagic Inc., USA); 3) Submitting the final model for 3D printing; 4) Conducting gait analysis and testing clinical effect. The process of obtaining the custom-fit

AFO is illustrated in Figure 1.

2.3. 3D printing of AFOs

The printing material was 3D High Reusability PA 12 (HP) [18]. All the AFOs were manufactured using Multi Jet Fusion (MJF) machine (Jet Fusion 3D 4200, HP, USA). Material PA 12 was engineering-grade thermoplastics which was strong and lightweight with a high elongation before the breaking point [19]. Material PA 12 was used to produce accurate parts with a high feature resolution [20]. According to previous research from Faustini and colleagues [11], rotational stiffness, energy dissipation and deconstructive testing platforms were set to evaluate AFO mechanical property. We had done a lab testing on mechanical properties of our AFO and detailed lab report could be found at Appendix.

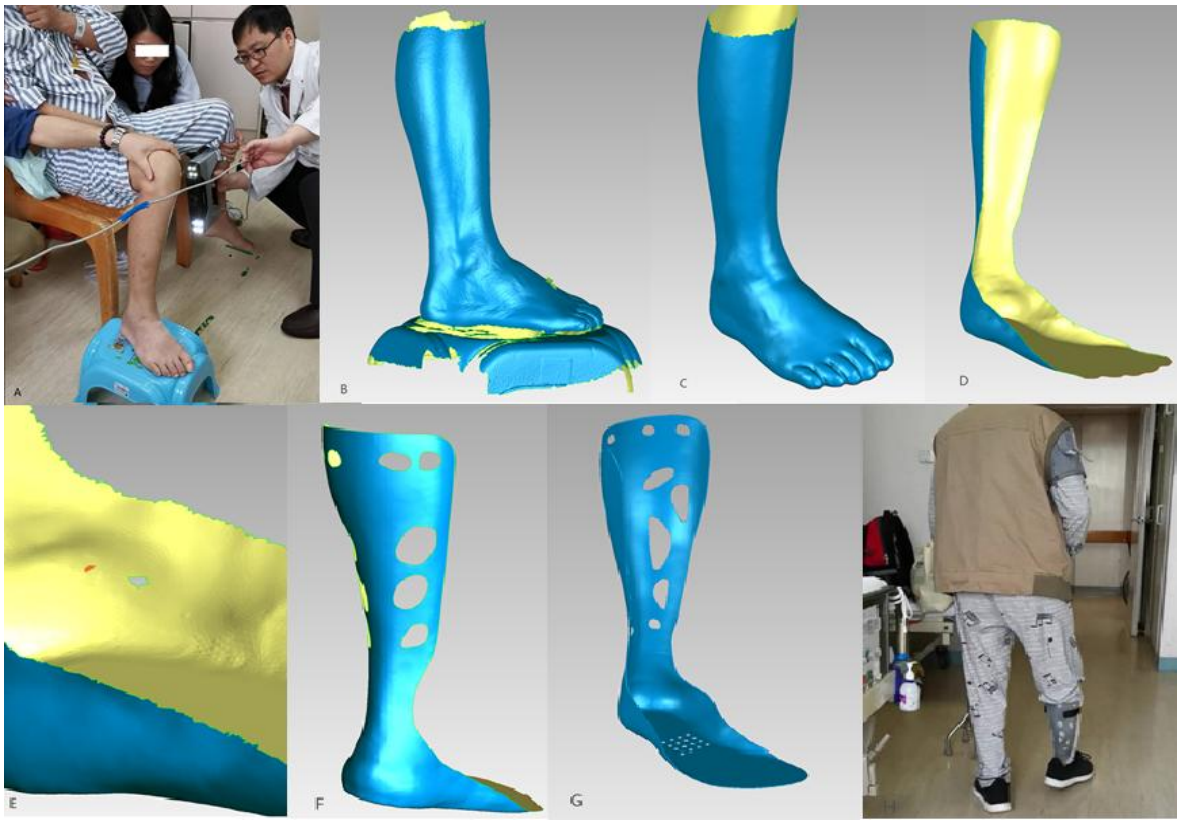

Figure 1. The process of additive manufacturing of AFO. A: 3D scan; B: raw data; C,D: delete the redundant data; E: repair the holes; F: Smooth the boundary lines; G: final AFO model for 3D printing; H: AFO produced using PA 12.

2.4. Gait analysis

The AFOs fabricated using PA 12 were used for gait analysis to compare the effects with and without AFO. Gait analysis was conducted at the Department of Rehabilitation Medicine, The First People's Hospital of Foshan (Foshan, Guangdong, China). We collected data from the subjects walking before wearing AFO and after wearing AFO. Subjects were allowed to adapt to wearing the

AFOs for at least half an hour before data collection. The adverse reactions (pain, pressure ulcers, and fracture of orthosis) were also recorded. Gait parameters were measured using the Gait Watch system (Zhanghe Electric Appliance Company, Guangzhou, China). Seven IMU sensors (size 52 × 41.1 × 18.6mm, accelerator range +/− 2g, gyroscope range +/− 2000 dps, magnetometer range 0.88 GA, with angle accuracy 0.02 deg, with the accuracy of angle at 0.02 deg, data acquisition and processing module with transmission 104 FPS using Bluetooth 2.0) were bound to the sacrum, anterior side in the middle segment of the bilateral femoral femur, the median side at the proximal end of the bilateral tibia, and dorsal part of the bilateral foot. Before testing, the subjects were required to be at standing position with attention to the commands from the physiotherapist. Then, the patients were asked to walk 12 m in a straight line at a self-selected speed, with or without walking canes. The data sampling frequency was 500 Hz. The walking data of patients were collected synchronously, which were then transmitted to the software for analysis.

2.5. Outcome measures

Temporal-spatial parameters included velocity, cadence, stride length, gait cycle, double limb support phase, and step length difference [1–3,17]. Kinematic data of pelvis, hip, knee and ankle joint were also calculated at three dimensions and average of 6 gait cycles was presented.

2.6. Statistical analysis

Temporal-spatial parameters of gait were presented as mean and standard deviation ($\bar{X} \pm SD$).The mean differences of the temporal-spatial parameters before and after wearing AFO were compared using the paired t-test and mean differences with 95% confidence interval (95% CI) were derived. $P < 0.05$ (two-sided) is considered as statistically significant.

3. Results

3.1. Fabrication of AFOs

It took about 2 hours from processing the initial AFO model to the completion of final model design, and the printing time was about 8 hours. The printing thickness of the designed AFOs was 1.2 mm. All the AFOs manufactured using material PA12 showed excellent dimensional accuracy, good toughness and high strength. All the AFOs were lightweight. The average weights were 120g which was better than expected. Meanwhile, the material PA12 produced slightly flexible AFOs making it suitable for wearing (Figure 1H). The surface of the AFOs was not smooth, but does not affect the comfort of wearing them. All printed AFOs were matched to the patient's ankle and foot, and all patients had no symptoms such as skin pressure sores, breakage, etc. All patients were willing to wear AFO, and the compliance was good. No breakage occurred within 3 months.

3.2. Gait analysis

All the participants completed the study. With respect to the temporal-spatial parameters, the

velocity and stride length in the gait with AFO increased significantly as compared to the gait without AFO (P = 0.001, P = 0.002). The cadence increased, double limb support phase decreased, and the step length difference decreased in the gait with AFO; however, the difference was not statistically significant (P = 0.117, P = 0.075, P = 0.051) (Table 2, Figure 2). Figure 3 showed a typical subject's kinematic data of movement trajectory with AFO and without AFO at the affected side and the curves were from hip joint (flexion/extension, internal/external rotation, adduction/abduction), knee joint (flexion/extension) as well as ankle joint (flexion/extension, adduction/abduction).

Table 2. Comparison of parameters walking before and after wearing AFO.

	Before AFO	After AFO	Mean difference [95% CI]	p
Temporal-spatial parameters				
Velocity (m/s)	0.17 ± 0.06	0.20 ± 0.07	3.67 [1.80, 5.53]	**0.001**
Cadence (times/min)	47.0 ± 14.4	53.8 ± 15.5	6.83 [−2.01, 15.67]	0.117
Stride length (m)	0.43 ± 0.10	0.48 ± 0.11	4.50 [2.08, 6.92]	**0.002**
Gait cycle (s)	2.8 ± 1.1	2.5 ± 1.0	−0.33 [−0.79, 0.13]	0.143
Double limb support phase (%)	36.3 ± 5.6	33.6 ± 5.2	−2.75 [−5.83, 0.33]	0.075
Step length difference (m)	0.16 ± 0.12	0.10 ± 0.09	−5.67 [−11.36, 0.03]	0.051

Note: * indicates the significant difference (p<0.05) between parameters that walking with and without AFO.

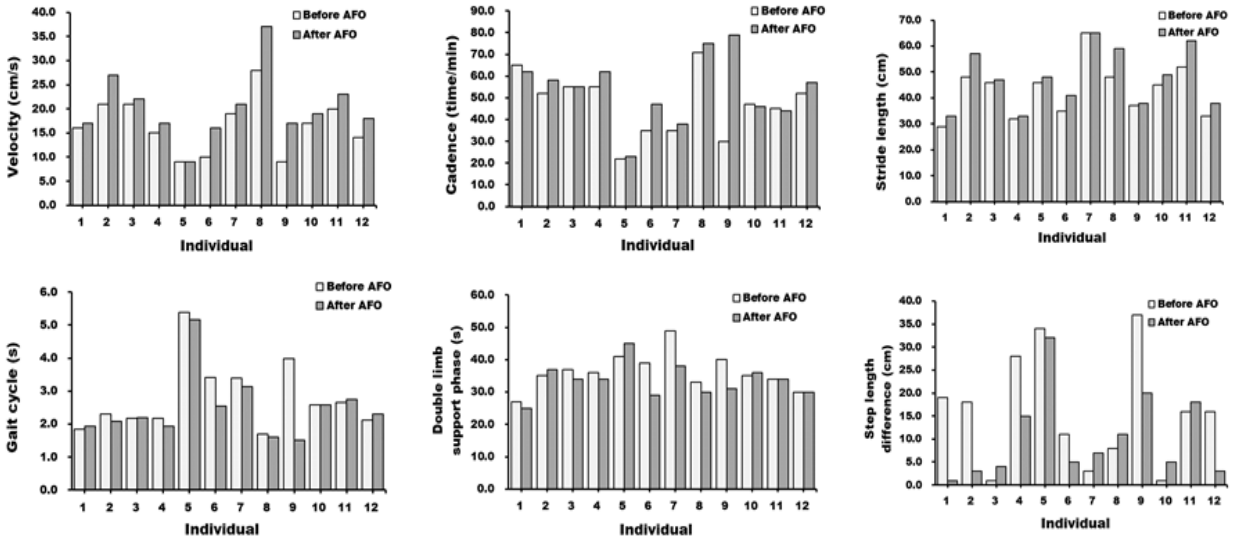

Figure 2. Detailed results of gait parameters included velocity, cadence, stride length, gait cycle, double limb support phase, and step length difference.

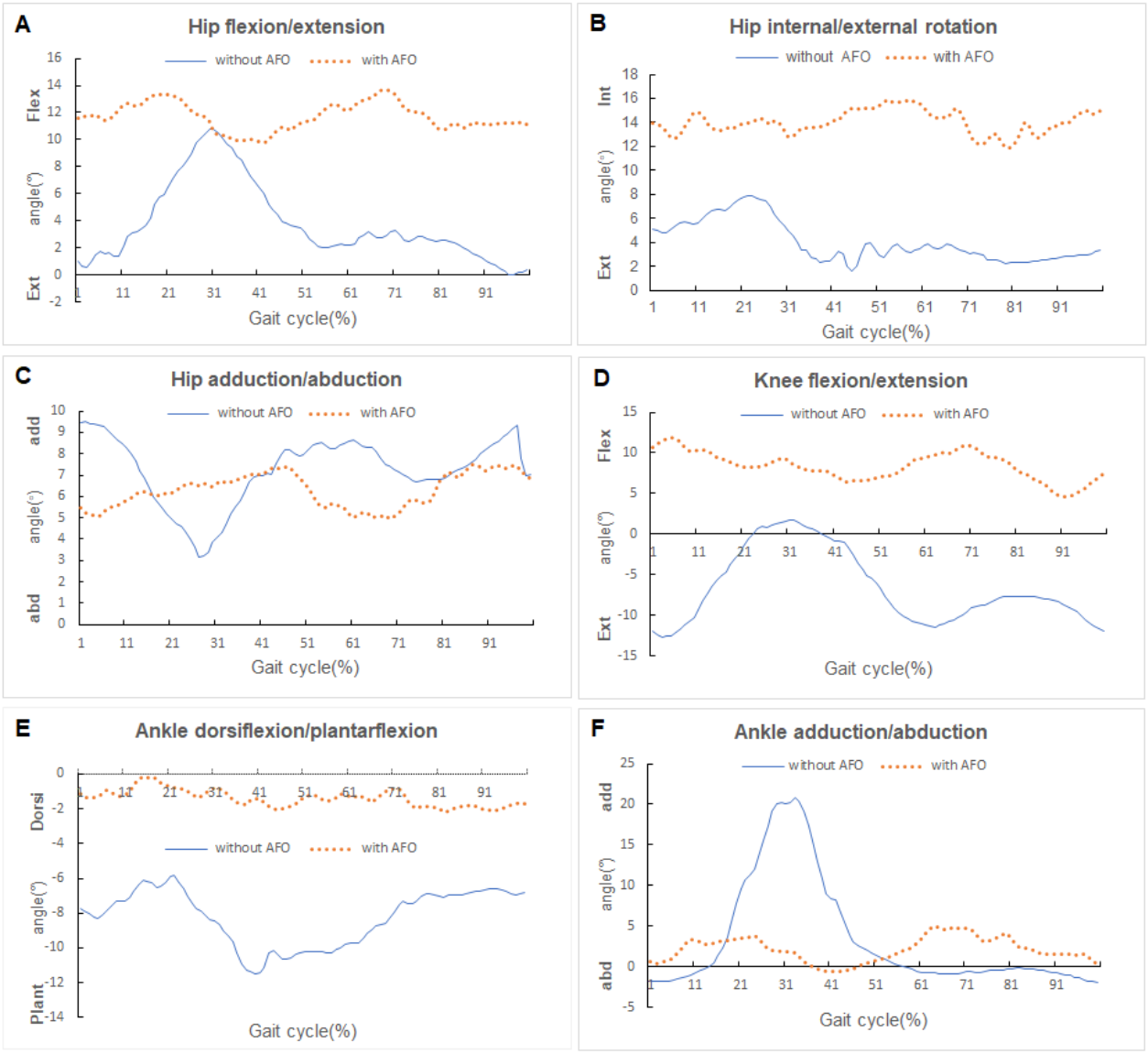

Figure 3. Joint angle curves (average of 4 gait cycles) of a typical male stroke survivors, with data from hip flexion/extension (A) hip internal/external rotation; (B) hip adduction/abduction; (C) knee flexion/extension; (D) ankle dorsiflexion/plantarflexion; (E) ankle adduction/abduction; (F) during gait with AFO and without AFO.

4. Discussion

Firstly, our study demonstrated the process of modifying AFO models. The software for CAD requires a high level of expertise, because raw data from 3D scanning must be manipulated to make a build file to be printed [3,7,8,12]. The keys to the processing AFO model were as follows: both sides of the AFO model must be designed to avoid the internal malleolus and external malleolus, and the two sides of the AFO were outwardly oriented to prevent from compressing the patient's skin. More importantly, the final printed AFO model displayed 8–10 small circular holes, each with a diameter of 2–3cm. The stress levels at the middle section of the posterior and lateral aspect of the AFO were higher than that in the others areas. Therefore, the small holes were designed at the two sides of the

upper and middle sections of the AFO. These holes were helpful for the ventilation and comfort of the user, simultaneously, they also contributed to a further reduction of weight and material cost. (Figure 2A,B,C).

Furthermore, we chose material PA12 to produce the AFOs. Previous studies indicated that a wide variety of printing materials and printing methods were applied in the fabrication process of AFOs [4,5,10–12]. For example, materials include PA2200 [4], PA2201 [14], DuraForm PA [5,10], DuraForm GF [10], Rilsan D80 [10], DuraForm EX Natural Plastic [11], Accura 40 resin and Somos 9120 [12]. In our study, the AFOs manufactured using material PA12 demonstrated adequate dimensional accuracy, toughness and high strength. The most satisfying thing was that the AFOs were lightweight and comfortable for the patient. As a result, we identified that material PA12 was appropriate printing material for AFO in clinical application.

The subsequent clinical trial showed that the 3D-printed AFO improved the walking function of the patients. In comparison to the gait without AFO, the velocity and stride length in the gait with AFO was increased significantly. In addition, the cadence had a trend of increase, and the gait cycle and double limb support phase were decreased. The step length difference was found to be decreased as compared to the gait without AFO, which also suggested a potential improvement in the walking ability with AFO (Table 2). In addition, we found the AFO could decrease the hip abduction, knee joint extension and ankle adduction (Figure 3). Similarly, Creylman [15] tested conventional thermoplastic AFOs and Selective Laser Sintering (SLS) AFOs on eight subjects with unilateral drop foot gait. A significant beneficial effect of customized SLS-AFO in terms of spatial temporal gait parameters including stride length and percentage stance phase duration compared to barefoot gait are observed. Mavroidis [13] tested two AFOs fabricated using material Accura 40 resin and Somos 9120. Their gait results on one subject showed equivalent walking speed, step length and doubled support time for AFOs made by stereolithography (SLA) in comparison with conventional AFO. Notably, our clinical trial evaluated only the immediate effects. Further testing of the long-term usage would be necessary to validate the advantage of the AFO.

This study had some limitations: (1) The shape of the 3D-printed AFO was similar to the traditional static AFO. In future study, we would further take the advantage of the computer digital technology to design a variety of complex structures and shapes according to the needs of the patients [11,21,22]; (2) Only a small number of stroke cases were tested, and clinical effects of 3D-printed AFO applied in current study and conventional AFO from other technologies were not compared due to the clinical availability of previous materials such as Accura 40 resin and Somos 9120. Further large scale of stroke samples as well as a long-term follow-up would be warrant; (3) This is only a preliminary study and we did not provide the lower limb kinematics data from healthy age-matched using the same gait analysis system. Then it is hard to compare the outcome from AFO without reference/control data. In future study, we will have the data from healthy subjects and record global parameters such as the range of motion to describe the restriction in ankle motion due to the AFO.

5. Conclusions

This study confirmed the feasibility of patient-specific AFO fabricated by AM techniques, and demonstrated the process of modifying AFO models successfully. The specific ankle-foot orthoses fabricated by material PA12 have a significant effect on the improvement of velocity and stride

length in people with stroke. The results of current study would provide useful information for the clinical application of AM technology.

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Conflict of interests

The authors declare that they have no competing interests.

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