

Manuscript title: The effect of three dimensional printing hinged ankle foot orthosis in chronic stroke patients

Jimmy Chun-Ming Fu

Kaohsiung Medical University Chung-Ho Memorial Hospital

Cyuan-Fong Li

Kaohsiung Medical University Chung-Ho Memorial Hospital

Yu-Hsuan Hsiao

Kaohsiung Medical University Chung-Ho Memorial Hospital

Feng-Zu Sheen

Kaohsiung Medical University Chung-Ho Memorial Hospital

Yi-Jen Chen

Kaohsiung Municipal Siaogang Hospital

Chia-Hsin Chen (✉ chchen@kmu.edu.tw)

Kaohsiung Medical University Chung-Ho Memorial Hospital

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Abstract

Background

Three-dimensional printing (3DP) is a promising technique utilized in orthosis fabrication, including ankle foot orthosis for stroke patients. However, the effects on ankle biomechanics remains unclear.

Objectives

To compare the plantar pressure distribution and patient's subjective experience in chronic stroke patients during 3DP hinged ankle foot orthosis (3DP-HAFO) and anterior ankle foot orthosis (A-AFO) walking

Methods

Ten patients with first-ever unilateral stroke were enrolled in this study. All patients performed 10-meter walk test in 3 different conditions, including 3DP-HAFO walking, A-AFO walking, and bare foot walking. The plantar pressure parameters including contact area, maximum force, and peak pressure were collected using Pedar X insole system. Gait asymmetry analysis of the plantar pressure parameters was conducted. Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) was used for patient's satisfaction.

Results

3DP-HAFO walking revealed significant increase in medial midfoot peak pressure compared to bare foot walking. Gait asymmetry analysis illustrated more even medial midfoot contact area during 3DP-HAFO walking compared to bare foot walking while A-AFO walking did not. In QUEST survey, 3DP-HAFO outweighs A-AFO in fitting and durability.

Conclusions

3DP-HAFO may improve ankle instability and gait asymmetry in chronic stroke patients.

Introduction

Stroke is the second leading cause of death worldwide, and the sequela of stroke is one of the main causes of adult disability, with up to 50% of stroke survivors being chronically disabled ¹. Post-stroke hemiplegia remains a long-term complication of stroke, which limits the patient's physical performance and mobility in daily life ². The restoration of functional ambulation is one of the priorities while setting rehabilitation goals in post-stroke patients. Ankle foot orthosis (AFO) is an orthotic device commonly fabricated to provide ankle stability during stance phase of gait cycle, and facilitate foot clearance during swing phase ^{3,4}.

Patients with stroke often wear the anterior leaf type AFO, called anterior AFO (A-AFO), for ankle support during ambulation after their condition become stabilized ⁵. These orthoses improve the stability of ankle joints through drop foot reduction and the ability of lateral weight shifting through mediolateral support ⁶. While A-AFO has above advantages, there are some pitfalls wearing A-AFO. Since the A-AFO is designed to protect and immobilize affected ankle joints, dynamic flexion is limited. Moreover, there are no dynamic hinges designed in A-AFO, the range of ankle dorsiflexion and plantarflexion is restricted. The ankle support may not be enough because of lack of coverage at the heel. In addition, A-AFO is handmade, which let the contour and the size be slightly different from each product. This probably will disturb patients once changing new A-AFO.

The three-dimensional printing (3DP) technique, one of the most recent computer aided manufacturing techniques, has been introduced with emerging approaches to fabricate components of custom foot orthosis. Orthoses made with 3DP technique have several advantages, including easy production without the need of delicate skill compared with hand-made orthoses, easy reproduction with consistent quality once personalized 3DP modeling file was built and mass customized. The dimensional accuracy and manufacturing precision of 3DP technique has been validated ⁷. Recent study illustrated that 3DP orthosis has positive subjective comfort rating ⁸. Use of 3DP ankle foot orthosis (3DP-AFO) has shown at least equivalent performance to the handcrafted posterior leaf AFO ⁹. However, the effect of 3DP-AFO compared with A-AFO is not reported. Also, it is unclear whether 3DP-AFO could affect plantar pressure distribution in stroke population.

In this study, we fabricated a 3DP-AFO with hinge and posterior leaf design (3DP-HAFO) to compare plantar pressure distribution and gait asymmetry among stroke patients wearing 3DP-HAFO, A-AFO or bare foot walking.

Methods

Participants

Participants were enrolled with confirmed diagnosis of stroke from brain computed tomography or magnetic resonance imaging. The inclusion criteria were as following: 1) first-ever unilateral stroke (hemorrhagic or ischemic), 2) 20 years or older, 3) at least 3 months after stroke, 4) Functional Ambulation Category score of 3 or more, and 5) Brunnstrom stage of lower extremity III-IV. Patients were excluded if they had presence of low extremities peripheral vascular disease, sequelae of previous neurologic or orthopedic disorder that could impair locomotion, joint contracture in the lower extremities, skin problems, severe cognitive or visuospatial dysfunction and/or severe medical illness. All participants were informed of the study and submitted a written informed consent.

Orthosis design and fabrication

Fabrication of three-dimensional printing hinged ankle-foot orthosis (3DP-HAFO)

First, we used 3D scanning system (Sense2 3D scanner, 3D SYSTEMS) to scan the shape of the affected leg to acquire 3D modelling file with triangle mesh architecture (Figure 1a). Then, orthosis software (Rhinoceros®, Robert McNeel & Associates) was loaded. Medial and lateral malleolus as anatomical landmarks were manually marked at the heel to perform standard positioning points and reference lines according to preprogrammed orthotic template design derived from anthropometric data of normal, healthy volunteers. Ankle joint axis was adjusted to a neutral position by eversion (Figure 1b). The AFO hinged joint component socket was designed and built for assembly after printing (Figure 1c). The designed AFO was printed using a fused filament fabrication (FFF) type 3D printer (MINGDER 3D Printing 500S). Poly lactic acid (MINGDER 3D Printing) was used as printing material (extruders temperature 155–170°C) (Figure 1d). After printing out the designed AFO, components were trimmed to smoothen surface and hinge joint was assembled (Figure 1e).

Fabrication of anterior ankle-foot orthosis (A-AFO)

Anterior AFO is an anterior leaf orthosis made of thermoplastic material (CMC medical devices, 3.2cm in thickness, 55 ° C-75 ° C in molding temperature). It is cropped and molded directly to the lower leg under sitting position, with knee flexion 90 degrees and ankle dorsiflexion 5 degrees. The pretibial pad was added to reduced friction. The sole was fabricated around metatarsal area just behind the metatarsal head.

Protocol

All participants walked on a 10-meter walkway under three conditions in a random order, including walking with 3DP-HAFO, walking with A-AFO, and walking without orthosis (bare foot walking). The 3DP-HAFO and A-AFO were applied to hemiplegic leg. All participants wore standard shoes during the tests. The pedar®-X (Novel GmbH, Munich, Germany) insoles were placed within each shoe beneath the sole. The participants completed four walking trials for each condition. Participants were timed as they walked at a comfortable self-selected speed along the walkway. To ensure consistency of walking speed, any trial was eliminated and repeated if the time differed by more than 5% of the original trial time. To familiarize with orthosis wearing, participants tried and adjusted between the 3DP-HAFO and A-AFO orthoses for at least one month, until they felt comfortable on the day before the trials.

Pressure analysis equipment

Plantar pressures were measured using the pedar®-X system (Novel GmbH, Munich, Germany), which has been demonstrated to be a valid and reliable in-shoe pressure measurement system as described in the literature^{10, 11}. The pedar®-X insole comprised of 99 capacitive sensors arranged in a grid and embedded within a thin flexible insole. The sampling frequency was 50 Hz. The pressure insoles were zeroed as described by the manufacturer's guidelines prior to the first walking trial of each condition. Measured plantar foot pressure data were transmitted by using a Bluetooth connection to a computer for recording.

Outcome measures

To determine gait performance with different AFO types, the gait speed and cadence were recorded during 3DP-HAFO walking, A-AFO walking and bare foot walking. The gait speed was calculated as time spent on 10-meter walking. The cadence was calculated as number of steps in one minute.

The contact area, maximum force, and peak pressure of each section were recorded. Data were compared in 4 mask regions corresponding to anatomically relevant areas of the foot (Figure 2), namely forefoot(distal 40% of foot length), lateral midfoot, medial midfoot, and hindfoot(proximal 27% of foot length), based on each participant's anteroposterior foot length. To determine gait asymmetry, plantar parameters were calculated following the formula below, where V indicated values of contact area, maximum force, and peak pressure in each section ¹²:

$$[(V_{\text{paretic}} - V_{\text{non-paretic}}) / 0.5(V_{\text{paretic}} + V_{\text{non-paretic}})] \times 100 (\%)$$

To evaluate participant satisfaction wearing different types of AFO, the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) was used ¹⁰. Each participant filled out the questionnaire during the out-patient clinic follow up approximately 2 months after orthosis wearing.

Statistical analysis

Statistical analysis was performed using Prism 8.0 for Windows (GraphPad Software, San Diego, USA). All measurements were analyzed for the difference among 3DP-HAFO walking, A-AFO walking and bare foot walking using Friedman test. Dunn's multiple comparisons test was used for post hoc analysis. The difference was considered statistically significant at $p < 0.05$.

Results

Participants basic demographics

The current study enrolled total 10 hemiplegic stroke participants, including 8 men and 2 women. The mean age of enrolled participants was 54 years old. The mean duration since stroke onset at the time of enrollment was 13 months. Four participants had ischemic stroke, and 6 had hemorrhagic stroke. The Brunnstorm motor recovery stages of affected lower extremities were stage III and IV (stage III in 5 participants, and stage IV in 5 participants). The Functional Ambulation Category was 3.1 (range 3-4). The manual muscle test of the affected ankle dorsiflexor ranged from poor grade to good grade. The Modified Ashworth scale of affected ankle joint ranged from 1~1+ (1 in five participants, 1+ in 5 participants). All participants were able to walk independently without cane under supervision, although different degrees of ankle inversion were observed in all participants during walking.

Changes in affected limb contact area, maximum force and peak pressure among different AFO types

The contact area of medial midfoot on the affected limb was significantly increased in both 3DP-HAFO ($p=0.01$) and A-AFO ($p=0.04$) walking compared to bare foot walking (Table 1). The maximum force of lateral midfoot on the affected limb was increased in A-AFO walking compared to bare foot walking ($p=0.04$), while those of 3DP-HAFO walking did not show significant difference (Table 2). In addition, the peak pressure at medial midfoot on the affected limb was significantly increased in 3DP-HAFO walking in comparison to bare foot walking ($p=0.01$), while the peak pressure at lateral midfoot on the affected limb showed significant increase in A-AFO walking in comparison to bare foot walking ($p=0.02$) (Table 3).

Changes in unaffected limb contact area, maximum force and peak pressure among different AFO types

The contact area of medial midfoot on the unaffected limb was significantly increased in 3DP-HAFO walking compared to A-AFO walking ($p=0.01$) and bare foot walking ($p=0.04$). The significant change in maximum force on the unaffected limb was observed only at the medial midfoot, with increased maximum force in 3DP-HAFO walking compared to bare foot walking ($p=0.04$). Also, the peak pressure was only observed to be significant different at the medial midfoot on the unaffected limb, with increased medial midfoot peak pressure in 3DP-HAFO walking compared to both A-AFO walking($p=0.04$) and bare foot walking($p=0.01$). The details of contact area, maximum force and peak pressure during three conditions of walking were shown in Table 1-3.

Gait asymmetry

In both 3DP-HAFO and A-AFO walking, significant change in the asymmetric index was observed only in the contact area of medial midfoot (Table 4). The asymmetric index of medial midfoot contact area were significantly improved in 3DP-HAFO as compared to barefoot walking ($p=0.04$), while A-AFO walking also revealed similar trend but failed to reach statistical significance.

Changes in gait performance among different AFO types

The gait speed and cadence during 3DP-HAFO walking, A-AFO walking and bare foot walking were shown in Table 5. There was no significance difference in gait speed and cadence among the three groups.

Participant's satisfaction

The questionnaire survey showed that participants felt 3DP-HAFO outweighed A-AFO in aspects of dimensions, durability, comfort and effectiveness. However, weight and convenience of wearing were two major concerns when wearing 3DP- HAFO (Table 6).

Discussion

In this study, we investigated the gait performance and plantar pressure effects of hinged AFO with 3DP technique and automated designed by CAD software on hemiplegic stroke population. The results suggested plantar pressure increased at medial midfoot with improved contact area asymmetry in 3DP-HAFO walking.

For stroke patients, walking with insufficient ankle dorsiflexion are common due to joint stiffness and spasticity¹³. Clinically, patients experienced forefoot drop with dynamic equinovarus deformity throughout all gait cycle¹⁴. The abnormal gait pattern in stroke patients result in loss of mid foot weight bearing in stance phase. In the current study, increased contact area and peak pressure at the medial midfoot was observed during 3DP-HAFO walking as compared to bare foot walking. Increased medial midfoot contact area was also found in A-AFO walking. However, peak pressure was not increased in medial foot area, but in lateral midfoot during A-AFO walking. These findings indicated that weight bearing is more in lateral side than in medial side in A-AFO walking compared to 3DP-HAFO walking. The results proposed that wearing 3DP-HAFO can partially correct dynamic equinovarus deformity and increase affected limb weight bearing, which can improve balance of affected limb during single stance phase.

Posterior leaf AFO design is as useful as A-AFO in balance control for stroke patients. Both types of AFO exert effects of decreased excessive ankle plantar flexions during swing and stance phase¹⁵. Adding hinge design on posterior leaf AFO can provide additional plantarflexion control by lever arm and reduce initial toe contact of stance phase in hemiplegic patients¹⁶. The hinged AFO rendered the greatest support of dorsiflexion during stance compared to posterior leaf and solid AFO¹⁷. Thus, both A-AFO and posterior design AFO can improve equinus foot pattern during walking. When it comes to inversion deformity, research revealed that A-AFO decreased ankle inversion during both stance and swing phases, while posterior AFO can only correct ankle inversion during swing phase¹⁸. Previous studies also support this perspective that A-AFO can enhance ankle medial-lateral control and improve ankle stability^{6,19}. Our finding illustrated that 3DP-HAFO can increase medial midfoot weight bearing compared to bare foot walking, and the effect was more significant in contrast to A-AFO walking, reflecting on decreased lateral midfoot peak pressure and increased medial midfoot peak pressure. The current evidence suggested that 3DP-HAFO can not only decrease ankle equinus pattern but also improve varus deformity. This finding has never been proposed in previous studies with posterior AFO without 3DP technique. The orthosis made of 3DP technique was more fit, which may provide better ankle medial-lateral control. Further investigation is necessary to validate the current findings.

Furthermore, stroke patients are prone to bear more weight on their unaffected leg²⁰⁻²². The asymmetry of the contact pressure and area was found in stroke patients due to decreased contact area, force and pressure of the affected side compared with unaffected side²³. The imbalance of weight distribution during walking will increase the risk of falling²². Training approaches emphasizing symmetric walking showed improvement of balance and functional outcomes^{24,25}. Symmetrical walking after stroke played a crucial role for functional restoration²⁶. In our study, the asymmetry of contact area was improved in 3DP-HAFO walking, suggesting that 3DP-HAFO walking may improve the gait through more symmetric weight distribution in both lower limbs. In contrast to A-AFO, 3DP-HAFO has stronger mid shank extension and may strengthen ankle stability and correct the dynamic equinovarus deformity during walking. The posterior leaf design of 3DP-HAFO may provide better sensory stimulation on hemiplegic patients' feet as compared to A-AFO design, which is fixed on foot arch²⁷⁻²⁹.

One of the outstanding characteristics of 3DP technique is individualization. In this study, 3DP-HAFO showed better satisfaction in comfort item in the QUEST compared to A-AFO. Although there is no difference in functional outcome of gait speed and cadence between 3DP-AFO and A-AFO walking, 3DP-HAFO outweighed A-AFO in items of effectiveness in the QUEST. The result implied that stability and balance, rather than gait speed, are the primary concerns to evaluate satisfaction of orthosis use in walking assist of hemiplegic stroke population. In addition, 3DP-HAFO was more durable than A-AFO. It may be attributed that 3DP-AFO was made from high temperature process, while A-AFO was made from low-temperature thermoplastic material. There are two drawbacks of our 3DP-HAFO. First, weight of 3DP-HAFO was heavier compared to A-AFO. This reflected on the QUEST. The other was the ease of using and adjustment. Due to posterior leaf design of 3DP-HAFO, participants needed more time to take on and off shoes when using 3DP-HAFO. Shoes selection was also restricted to flat sole to fit rigid orthotic bottom.

There are some limitations in the current study. As previous study showed that AFO has immediate effect in improving gait and balance³⁰, temporal follow up is not analyzed in this study. Moreover, kinematic and kinetic assessments were not performed for gait analysis. Thus, further investigation with longitudinal follow up is necessary to validate the current findings.

In conclusion, 3DP-HAFO may improve the ankle stability and gait symmetry, but not the gait speed. Further studies are warranted to determine whether long-term use of 3DP-HAFO and combined rehabilitation training are effective in improving the gait patterns and functional walking in hemiparetic stroke population.

Clinical Messages

Clinical Messages:

- 3DP is a feasible technique in ankle foot orthosis fabrication process.
- Wearing 3DP-HAFO may improve ankle medial lateral control and gait asymmetry in hemiplegic patients.
- 3DP-HAFO is more fit, comfortable, effective and durable compared to traditional A-AFO.

Declarations

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Competing interests: The authors declare that there is no conflict of interest.

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Ethics approval of research

This study was approved by Institutional Review Board in Kaohsiung Medical University Chung-Ho Memorial Hospital (Reference numbers: KMUHIRB-E(II)-20180257) according to the guidelines of the Declaration of Helsinki.

Methods were managed in accordance with the approved guidelines.

All patients and caregivers were provided with information about the procedures and purpose of this study and provided written informed consent before inclusion.

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Tables

Table 1. Comparison of contact area between 3DP-HAFO, A-AFO and bare foot walking

Contact Area [cm ²]	Affected leg							Unaffected leg						
	3DP-HAFO		A-AFO		Bare foot		P value	3DP-HAFO		A-AFO		Bare foot		P value
	Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	Mean	SD	
Forefoot	22.59	11.95	26.24	10.91	26.73	13.33	0.14	24.04	9.14	29.26	8.98	27.82	11.73	0.08
Medial midfoot	8.49*	4.12	7.28#	3.55	5.32	5.15	<0.001	9.90*+	4.70	7.69	5.27	7.93	5.90	<0.001
Lateral midfoot	16.69	5.91	16.13	4.07	14.09	5.10	0.14	18.64	3.80	17.02	2.89	17.59	5.41	0.19
Hindfoot	21.22	6.48	21.07	7.68	23.49	7.79	0.37	20.81	7.83	23.65	7.39	24.63	8.33	0.60
Total	69.03	21.40	70.75	18.95	70.17	26.82	0.22	73.42	15.78	77.71	13.54	78.55	24.83	0.14

* Significance between 3DP-HAFO v.s. bare foot

Significance between A-AFO v.s. bare foot

+ Significance between 3DP-HAFO v.s. A-AFO

Table 2. Comparison of maximum force between 3DP-HAFO, A-AFO and bare foot walking

Maximum force[N]	Affected leg							Unaffected leg						
	3DP-HAFO		A-AFO		Bare foot		P value	3DP-HAFO		A-AFO		Bare foot		P value
	Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	Mean	SD	
Forefoot	235.75	117.27	309.14	159.24	265.79	148.26	0.19	284.66	132.43	347.10	160.09	274.50	167.11	0.32
Medial midfoot	74.97	43.27	65.55	28.33	38.03	22.28	0.07	115.50*	105.39	75.48	80.35	69.88	76.32	0.03
Lateral midfoot	229.57	173.39	267.92#	155.21	148.64	109.15	0.03	264.38	136.90	221.55	101.23	188.14	126.61	0.32
Hindfoot	285.11	144.52	296.91	172.01	326.06	179.01	0.60	307.33	211.64	425.78	279.41	371.56	256.18	0.22
Total	724.91	377.70	822.81	358.40	704.59	395.13	0.71	895.56	427.38	988.89	462.33	823.40	522.91	0.97

* Significance between 3DP-HAFO v.s. bare foot

Significance between A-AFO v.s. bare foot

Table 3. Comparison of peak pressure between 3DP-HAFO, A-AFO and bare foot walking

Peak pressure[kPa]	Affected leg							Unaffected leg						
	3DP-HAFO		A-AFO		Bare foot		P value	3DP-HAFO		A-AFO		Bare foot		P value
	Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	Mean	SD	
Forefoot	312.67	219.48	269.06	147.74	215.73	111.75	0.97	245.71	147.08	239.05	119.70	190.56	83.06	0.71
Medial midfoot	126.94*	57.28	104.50	40.73	71.43	38.32	0.01	174.90*+	107.58	111.90	55.44	92.31	63.27	<0.001
Lateral midfoot	241.60	224.05	289.45#	210.91	135.54	110.99	0.02	218.37	109.88	191.50	85.83	152.26	77.32	0.32
Hindfoot	180.74	81.27	154.04	67.18	159.67	74.66	0.60	177.42	135.20	231.30	163.12	192.55	120.94	0.08
Total	374.21	254.95	378.75	192.04	262.65	125.41	0.44	334.25	170.75	329.15	176.56	296.23	111.51	0.83

* Significance between 3DP-HAFO v.s. bare foot

Significance between A-AFO v.s. bare foot

+ Significance between 3DP-HAFO v.s. A-AFO

Table 4. Asymmetric index of 3DP-HAFO, A-AFO and bare foot walking

		3DP-HAFO		A-AFO		Bare foot		
		Mean	SD	Mean	SD	Mean	SD	P value
Contact Area	Forefoot	43.09	33.39	32.95	25.28	39.92	26.52	0.19
	Medial midfoot	59.11*	61.40	62.26	49.50	112.00	61.77	0.05
	Lateral midfoot	21.33	19.64	16.45	12.70	23.36	20.10	0.97
	Hindfoot	54.21	49.20	31.46	23.74	30.03	38.33	0.60
Maximum force	Forefoot	47.22	30.33	35.55	30.71	50.48	39.90	0.44
	Medial midfoot	61.07	60.78	61.96	53.30	93.72	68.68	0.32
	Lateral midfoot	62.76	108.79	21.63	18.59	33.26	27.00	0.83
	Hindfoot	74.88	71.71	52.55	40.27	44.57	47.33	0.97
Peak pressure	Forefoot	72.54	97.82	25.35	19.31	31.66	25.05	0.44
	Medial midfoot	41.78	53.03	28.64	25.46	48.00	43.17	0.60
	Lateral midfoot	59.52	75.77	40.03	28.35	33.78	27.02	0.97
	Hindfoot	43.58	26.97	48.20	33.49	43.19	36.84	0.97

* Significance between 3DP-HAFO v.s. bare foot

Table 5. Comparison of gait speed and cadence of 3DP-HAFO, A-AFO and bare foot walking

		3DP-HAFO		A-AFO		Bare foot		
		Mean	SD	Mean	SD	Mean	SD	P value
Speed (m/s)		0.28	0.14	0.28	0.14	0.29	0.16	0.97
Cadence (steps/min)		64.88	21.37	65.77	20.13	70.78	18.59	0.60

Table 6. Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) in 3DP-HAFO and A-AFO

QUEST	3DP-HAFO		A-AFO		P value
	Mean	SD	Mean	SD	
1.the dimensions (size, height, length, width) of your assistive device?	4.0	0.94	3.7	0.48	0.53
2.the weight of your assistive device?	2.8	0.63	3.7	0.82	0.06
3. the ease in adjusting (fixing, fastening) the parts of	3.2	1.03	3.8	0.92	0.31
4. how safe and secure your assistive device is?	3.6	0.52	3.6	0.84	>0.99
5. the durability (endurance, resistance to wear) of your	3.5	0.71	3.1	0.74	0.36
6. how easy it is to use your assistive device?	3.0	0.82	3.9	0.99	0.08
7. how comfortable your assistive device is?	3.5	1.08	3.2	0.63	0.67
8. how effective your assistive device is (the degree to which your device meets your needs)?	3.7	0.48	3.2	1.03	0.24

Figures

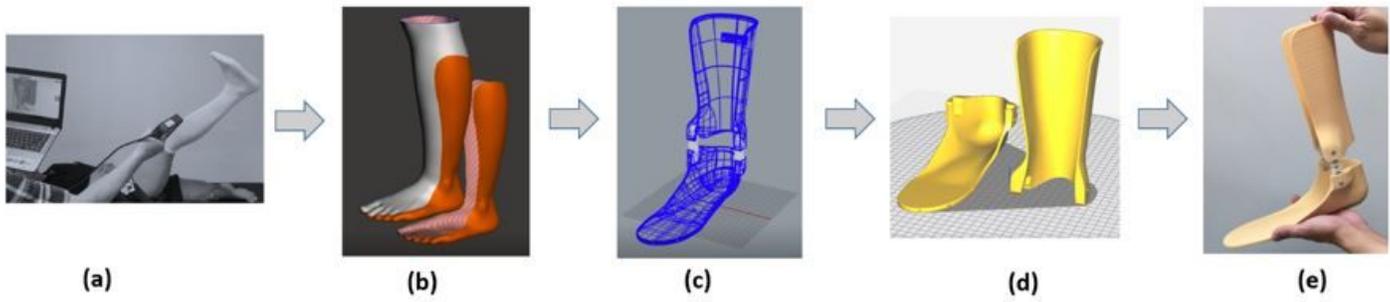


Figure 1

Manufacture process of 3DP-HAFO. (a) 3D scan, (b) build 3D orthosis template, (c) AFO hinged joint design, (d) print orthosis components, and (e) assemble orthosis with hinge joint.

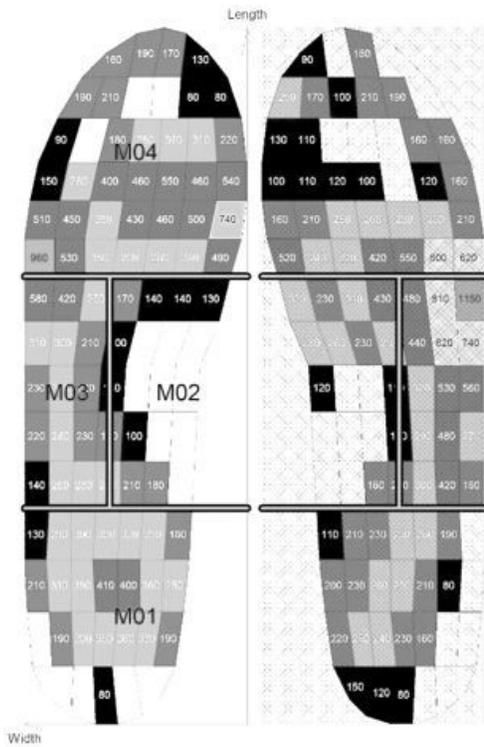


Figure 2

The 4 mask areas of the foot shown by one of the participant's data (M01) Hindfoot, (M02) Medial midfoot, (M03) Medial midfoot (M04) Forefoot.