Design and development of an affordable customized EVA shoes for Individuals suffering from a non-flexible "Metatarsus Adductus"

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Abstract

In this work, an affordable modified Ethylene-vinyl acetate (EVA) shoe was designed and developed for the persons suffering from "Metatarsus Adductus" foot deformity. The effects of developed shoes on the subjects gait parameters (i.e., speed, stride length, step length, double support time, and hip, knee, and ankle movement) were analyzed. The study involved measuring the subjects foot morphology, manufacturing custom EVA shoes, and presenting factors that helped reduce the cost of custom-made shoes while enhancing the subjects comfort. The stiffness of the lateral portion of the sole was modified to balance load distribution in the plantar region. Additionally, an inverted heel provision was incorporated to address excessive pronation moments. Gait analysis was conducted using a marker less pose estimation algorithm in different shod conditions (i.e., regular closed-toe shoes, open-toe slippers, and the modified/customized EVA shoes). The results were statistically analyzed using a two-sample t-test, and Bland-Altman analysis was performed to identify fixed and proportional biases in the dataset. To validate test reliability, the Intraclass Correlation Coefficient (ICC (3,1)) (Two-way mixed effects, single rater) was also calculated. The results confirmed that the modified EVA footwear positively impacted the subjects ambulatory movement (e.g., increased step length, stride length, and range of motion), which was further supported by the subjects feedback. This work provides valuable insights into low-cost manufacturing of both regular and customized footwear.

Keywords Bespoke shoes, Shoe customization, Ethylene-vinyl acetate (EVA) shoes, foot deformity, specialty Shoe manufacturing, Gait analysis, Marker less pose estimation

Introduction

Historically, metatarsus adductus, metatarsus varus [6, 21], metatarsus adductovarus [15], metatarsus supinatus [22], forefoot adductus [17], and hooked forefoot [23] are names commonly used for medial deviation of the forefoot. In all these synonyms, the deformity is located at Lisfranc's joint in a pure transverse plan, the metatarsals (Forefoot) are regularly adducted, and the hindfoot is normally positioned under the ankle joint and the leg (Figure 1(a)). Therefore, the pure transverse plane deformity at Lisfranc's joint without other abnormalities of the foot is called metatarsus adductus [9, 19]. In severe cases, it demonstrates a clinical stiffness and results in a Z-shaped foot (Figure 1(b,c)), where the valgus of the heel creates equilibration of resistant metatarsus adductus [10].

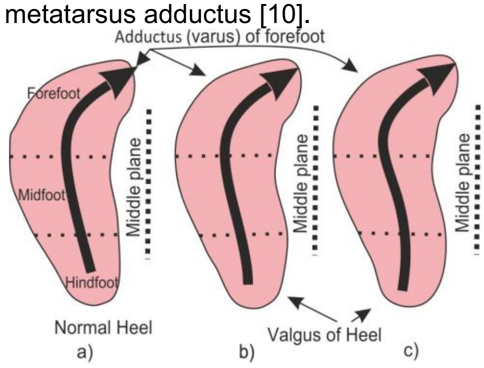

Fig. 1 Progress of Metatarsal adductus from normal-(a) to severe level (z-foot) –(c)

As per the range of motion of “Metatarsus Adductus” it can be divided into two categories. i.e., flexible and non-flexible [26]. In Flexible Metatarsus Adductus, the foot can be straightened up manually. Relatively this condition arises in early childhood and is usually painless. This condition may either be self-cured over time or can be cured by exercise or orthosis suggested by a trained physician / pedorthist. In the non-flexible Metatarsus Adductus, the foot is stiff and doesn’t return to its normal position with manual force. In this condition patients usually feel pain and available footwear options are also very limited. In such a condition, the subject is left with only two options: surgery or custom-made shoes. Surgery is an expensive solution, and not everyone can afford it, leaving custom-made shoes as the only viable option. However, even custom-made shoes are not a cheap alternative. Most of the time lower and middle class people cannot afford either the expensive surgery or able to purchase costly custom-made shoes. Keeping this problem in mind, we propose an affordable, low-cost customized Ethylene-vinyl acetate (EVA) shoes. EVA is a relatively very affordable material for making custom-made shoes. This study outlines all aspects of creating an affordable custom-made shoe and modifies it based on the subjects foot profile and specific requirements. Additionally, the impact of the modified footwear on the subjects walking gait was also analysed. Mostly the subjects feel uncomfortable in normal closed-toe footwear and always prefers either to remain barefoot or wear open-toe slippers/sandals. However, during winter and rainy seasons, open-toe footwear is not comfortable, and there is also a risk of being bitten by poisonous creatures. In this work, we have developed and modified a low-cost shoe based on the subject’s foot profile. While wearing this modified shoe, the subjects spatiotemporal and kinematic parameters were recorded as they walked. These parameters were then compared with those obtained while wearing regular shoes and open-toe sandals.

We have established two hypotheses in this study:

First Hypothesis: Null Hypothesis (A): There is no difference in subjects spatiotemporal and kinematic parameters in different shod conditions (i.e., regular shoes, modified shoes, and open-toe sandals).

Null Hypothesis (B): Modified shoes have no effect on the subjects ambulatory movement.

Materials and methods

Subjects selection

In this study, we selected subjects with metatarsus adductus or bean-shaped foot deformities in their feet (Figure 2(a)). Due to the deformity, the right and left foot shows a more pronounced curve. The subjects volunteered for the study and, aside from their foot conditions, are physically fit and does not have any other ambulatory impairments. The study protocol was approved by the local institutional ethics committee.

Custom made Last

The human foot is the most complex musculoskeletal structure of the human body, making custom shoe-last design a challenging task. A well-shaped shoe-last is essential for creating custom shoes. Traditionally, shoe-lasts are made from wood or plastic and shaped to match the foot profile, these lasts are costly and time-intensive to produce. Here, we optimise this process using Plaster of Paris (POP), an affordable, easily mouldable material that becomes hard and durable once dried (Figure 2(b)).

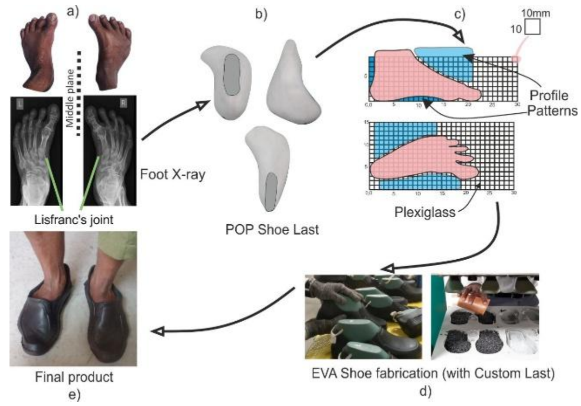

Fig. 2 (a) Subject Left and Right foot images and corresponding X-rays; (b) POP shoe-last made according to subject's foot profile; (c) Subject foot profile patterns traced with plexiglass box markings; (d) EVA shoes manufacturing (e) subject wearing customized EVA shoes, modified according to subject's foot profile.

Measurements of Foot

The next crucial aspect in making properly fitted custom shoes is the precise measurement of the foot's morphological parameters. To measure foot morphology, conventional tools like calipers, scales, and measuring tape are commonly used. while more recent laser and optical scanners provide high accuracy and are relatively faster, though they are costly and require technical expertise. Both approaches are either time-consuming or expensive. Instead, here we are using a transparent plexiglass box (Figure 2(c)) to measure key foot parameters. On the plexiglass box, the grids marked on each side of the box represent units of 10 x 10 mm, with a total grid size of 300 x 150 mm (30 x 15 units). The subject steps into the box according to the pre-defined reference lines, and foot images have been recorded along the sagittal, frontal, and horizontal planes parallel to the foot. The recorded data was used to calculate the foot arches and structural measurements (e.g., length, girth, width, medial malleolus height, lateral malleolus height etc.) based on the covered grid unit's area marked in the Plexiglas box image. The resulting measurements guide pattern creation, simulating foot curvatures, and aid in the precise trimming of the shoe-last. These patterns significantly reduce the risk of over-trimming or under-trimming during shoe-last shaping.

EVA shoes manufacturing process

Now after the custom-made shoe-last is completed. The next stage is EVA shoe moulding. Ethylene-Vinyl Acetate (EVA) pallets are measured according to the size of the shoes and the mould cavity gets filled with it (Figure 2(d)). During pressing operation both lower and upper moulding plates must maintain a temperature difference of 5 − 60C (upper plate temperature =1330C, lower plate temperature =1390C.). The fresh moulded shoes is taken out from the compression moulding press and then the customised shoeslast gets inserted into it. At the initial stage, the EVA shoes is flexible enough to take the last shape. After EVA material reached normal temperature and takes its shape, the shoe-last gets removed from it. The subject wearing the customized shoes can be seen in (Figure 2(e)).

Study parameters:

In this study, spatiotemporal and kinematic parameters such as walking speed, stride length, step length, double support time, and hip, knee, and ankle angles were chosen to assess the effects of modified shoes on the subject's natural walking. Spatiotemporal parameters (stride length, step length, double support time) provide essential information about walking characteristics such as imbalance, walking efficiency, and joint mobility [1, 7]. Similarly, kinematic parameters (hip, knee, and ankle range of motion) are crucial for assessing gait efficiency and stability (Reduced ROM due to stiffness or pain can lead to shortened steps) [18, 24]. The parameters used in the study are defined in the Table 1.

Table 1 Definitions of study parameters

Study parameter Definition	Study parameter Definition
Spatiotemporal parameters:	
Walking speed (m/sec)	Refers to the distance a person covers over a certain period.
Stride length (cm)	The distance covered between two consecutive placements of the same foot while walking.
Step length (cm)	The distance between the point of initial contact of one foot and the point of initial contact of the opposite foot during a walking.
Double support time (sec)	Refers to a period during walking when both feet are in contact with the ground simultaneously.
Kinematic parameters:	
Hip angle (Degree)	
Flexion:	Refers to the movement when the leg is raised forward in front of the body, bringing the thigh closer to the chest.
Extension:	Refers to the movement when the leg moves backwards behind the body (opposite direction of hip flexion).
Knee angle (Degree)	
Flexion:	Knee flexion is the process of bending the knee joint, which reduces the angle between the thigh and the lower leg.
Extension:	Knee extension is the process of straightening the knee joint, increasing the angle between the thigh and the lower leg.
Ankle Angle (Degree)	
Dorsiflexion:	Refers to the movement where the toes and foot are lifted upwards towards the shin, decreasing the angle between the foot and the lower leg.
Plantarflexion:	Refers to the movement where the foot points downward away from the shin, increasing the angle between the foot and the lower leg.

Subject-specific shoes modification:
Sole stiffness:

During trials, it has been observed that the shoes were tilted laterally towards the outward direction. This happened because of the shape of the subjects foot, the center of mass (CG) has been shifted towards the lateral direction. Therefore, to counter this issue a stiffer material (rubber sheet) has been inserted in the lateral side of the sole (Figure 3(a)). The main objective of inserting the stiffer material is to counter balance the lateral moment exerted by the subject's foot and provide support and comfort by restricting excessive movement of forefoot portion. Haley et al. [8] have studied the effect of sole stiffness on metatarsophalangeal joint movement and reported that stiffer sole reduces the metatarsophalangeal joint movement. In the present study stiffer sole and toe spring provide extra support to the subjects foot by supporting subjects natural rocker movement.

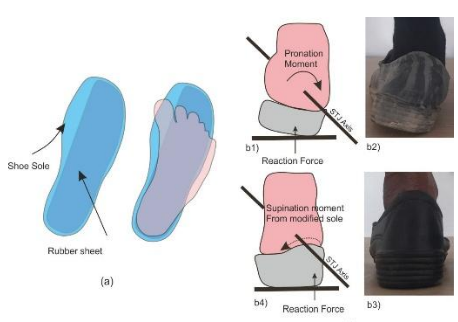

Fig. 3 (a)Rubber sheet inserted at the lateral side of shoes sole to enhance sole lateral stiffness. (b1, b2) Foot pronation due to excessive pronation moment, (b3, b4) Integrated inverted heel cup provided in shoes sole to exert supination moment to counter balance the pronation moment.

Inverted heel cup:

The pronation moment in the subjects left and right foot were observed (Figure 3(b1, b2)). To overcome this issue inverted heel cups are added to the inner side of the foot (heel area). These raised inverted heel cups lift the heel from the inner side, creating a slight outward tilt (supination moment) to counteract excessive inward rolling (pronation moment) (Figure 3(b3, b4)). Black et al. [2–4] presented pioneering work on counterbalancing pronation moments using inverted orthosis. Brauner et al. [5] demonstrated studies using inverted heel cups to counteract excessive pronation moments by creating a supination moment. In this work heel cups provisions were made in shoe-last during last preparation according to the foot profile.

Data collection and pre-processing:

In this study, the subjects performed three gait trials at intervals of 3-4 days. The subjects were asked to walk at their natural pace (comfortable condition) on a 10- meter-long pathway (while wearing regular shoes, open-toe sandals, and modified shoes). At both ends of the pathway, 0.5-meter distance marks were indicated, where the subject would take a U-turn and continue walking at a natural pace (Figure 4(a)). During this walk, a video clip of the subject passing from left to right in front of the camera (focus area) was trimmed to capture one gait cycle, which was then analysed. This process was repeated for three different trials under each condition, and 15 gait cycles were trimmed and analysed. The results were calculated based on the average of these cycles. To study spatiotemporal parameters, step length and stride length were calculated using the video clips and the reference markings on the background and ground floor (Figure 4(a)). Based on the time captured in the video, gait cycle time, walking speed, and double support time were computed. Kinematic parameters (i.e., Hip, Knee and Ankle movement) were analysed using a markerless pose estimation framework-MediaPipe. All video segments were rendered at a fixed frame rate (50 FPS). During the analysis a Butterworth low-pass filter was applied to remove the noise in captured data.

MediaPipe Pose estimation framework:

The MediaPipe Pose detection model works by detecting key landmarks on the human body (Figure 4(b,c,d)), which correspond to various joints and body parts. These landmarks are then used to estimate the range of motion and joint angles. This library/ platform utilizes a deep learning model that provides high accuracy in detecting and tracking 33 key landmarks on the body (Figure 4(c)). Each landmark has an associated (x, y, z) coordinate, where x and y represent the landmark's position in the image, and z represents the depth (relative distance from the camera).

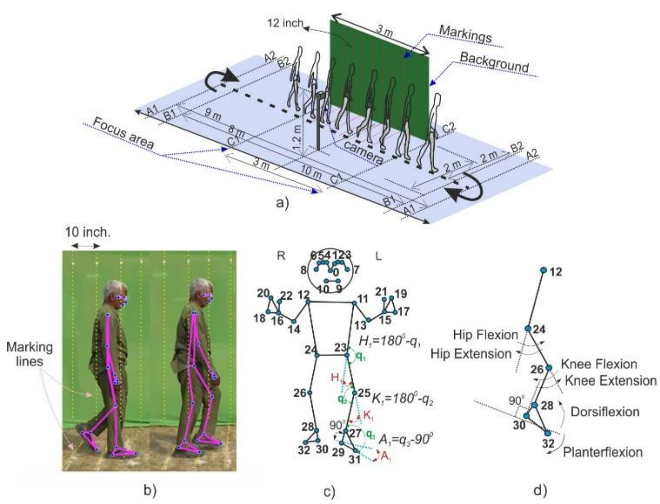

Fig. 4 (a) Gait trial setup with markings lines in background; (b) Subject walking clip processed with MediaPipe, background marking lines used for spatiotemporal parameter calculation; (c)MediaPipe landmarks (33 landmarks); 0 to 10 - facial; 13 to 21 and 14 to 22 - hand and elbow (Left and Right); 11,12

- Shoulder (L & R); 23,24 - Hip (L & R); 27,28 - Ankle (L & R); 29,30 - Heel (L & R); 31,32 - Toe (L & R). Hip angle (H1) = 1800 −q1 , Knee angle (K1) = 1800 −q2 , Ankle angle (A1) = q3 −900 ; (d) Lower extremity range of motion; Hip, Knee and Ankle movement.

Results:

The spatiotemporal and kinematic values obtained during the trials, including mean and standard deviation, are listed in the Table 2. The reference value of healthy males as per similar age and Body Mass Index (BMI) is included in the Table 2. Based on data obtained during three trials, each parameter displayed moderate to good intraclass correlation (ICC = 0.65 to 0.85) (Table 2). In comparing spatiotemporal data from modified vs. regular shoes and modified shoes vs. open-toe sandals, all parameters, except double support time, displayed statistically significant differences ($p < 0.05$) based on a two-sample t-test. (Table 2). For kinematic parameters, significant differences were observed between modified and regular footwear in hip, knee, and ankle range of motion (p-value < 0.05). Additionally, a statistically significant difference was found between modified and open-toe sandals for hip and ankle range of motion. The fixed and proportional biases between spatiotemporal and kinematic parameters obtained via Bland-Altman analysis for modified vs. regular shoes and modified shoes vs. open-toe sandals are shown in Table 3 and 4 respectively. For all three trials, if the level of significance was considerable (P-value < 0.05), those results were highlighted and used for drawing study inferences.

Table 2: Mean, Standard deviation and Intraclass correlation coefficient (ICC (3, 1)) of spatiotemporal and kinematic parameters during Regular shoes, Modified shoes and Open-Toe sandal. RV- Reference value of healthy male as per similar age group and BMI. (10 randomly chosen gait cycles per trial were used for the mean, standard deviation, and ICC calculation)

	Regular shoes (RS)		Open-Toe sandal (OTS)		Modified shoes (MS)			Two Sample t-test	
	(M, σ)	ICC(3,1) [95% CI]	(M, σ)	ICC(3,1) [95% CI]	(M, σ)	ICC(3,1) [95% CI]	RV [1]	MS Vs RS	MS Vs OTS
Speed(m/s)	0.8, 0.031	0.61 [0.24 0.87]	0.98, 0.06	0.8 [0.53 0.94]	1.14,0.07	0.79 [0.52 0.94]	1.15 + 0.15	P-val=0	P-val=0
Stride length (cm)	65.34, 3.70	0.61 [0.24 0.87]	92.06,4.2	0.79 [0.52 0.94]	112.96.3.66	0.86 [0.66 0.96]	122 + 2.5	P-val= 0	P-val= 0
Step length (cm) [L]	40.52, 1.36	0.8 [0.54 0.94]	45.61, 1.47	0.64 [0.28 0.88]	60.74, 1.20	0.85 [0.64 0.96	60 + 3	P-val= 0	P-val= 0
Step length (cm) [R]	25.91, 1.16	0.72 [0.39 0.91]	44.09, 1.36	0.6 [0.23 0.87]	59.14, 1.48	0.74 [0.55 0.9]	60 + 3	P-val= 0	P-val= 0
DS Time.(sec)	0.25	0.8 (0.54 0.94)	0.25	0.72 (0.39 0.91)	0.24	0.7 [0.36 0.9]	0.26 + 0.04	P-val= 0.5	P-val= 0.4
Hip angle (Degree)									
Flexion	17.93, 2.41	0.75 [0.44 0.92]	23.35, 0.47	0.6 [0.23 0.87]	28.97,0.64	0.72 [0.4 0.91]	25 + 5	P-val= 0	P-val= 0
Extension	-8.2, 0.28	0.86 [0.65 0.96	-10.11, 0.49	0.55 [0.16 0.84]	-11.69, 0.61	0.75 [0.45 0.92	12.5 + 2.5	P-val= 0	P-val= 0.12
Range	26.13, 1.52	0.7 [0.36 0.9]	33.46, 0.65	0.8 [0.53 0.94]	40.66, 0.85	0.79 [0.52 0.94]	35 + 5	P-val= 0	P-val= 0
Knee angle (Degree)									
Flexion	55.07, 0.82	0.82 [0.57 0.95]	55.49,0.94	0.8 [0.54 0.94]	57.13, 1.19	0.72 [0.4 0.91]	62.5 + 2.5	P-val= 0	P-val= 0.31
Extension	3.2, 0.59	0.7 [0.36 0.9]	3.07, 0.44	0.7 [0.36 0.9]	3.11, 0.58	0.62 [0.25 0.87]	2.5 + 2.5	P-val= 0.93	P-val= 0.43
Range	58.27, 0.81	0.77 [0.48 0.93]	58.56, 1.05	0.83 [0.6 0.95]	60.24, 1.28	0.61 [0.24 0.87]	65 + 5	P-val= 0	P-val= 0.13
Ankle angle (Degree)									
Dorsiflexion	7.09 0.19	0.6 [0.23 0.87]	10.2, 0.62	0.64 [0.28 0.88]	8.9, 0.49	0.54 00 15 0.84	12.5 + 2.5	P-val= 0.11	P-val= 0.03
Plantarflexion	-5.73 0.5	0.76 [0.46 0.93]	-12.23, 1.2	0.72 [0.39 0.91]	-7.95, 1.06	0.88 [0.69 0.96]	20 + 5	P-val= 0	P-val= 0
range	12.8 0.57	0.64 [0.28 0.88]	22.5, 2	0.61 [0.23 0.87	16.85, 1.38	0.6 [0.23 0.87]	30 + 5	P-val= 0	P-val= 0

Abbreviations: M = mean, σ = Std. dv, ICC = Intraclass correlation coefficient, CI = confidence interval RV = Reference value (healthy male) MF= Modified Footwear, RF = Regular Footwear, OTS = Open − Toe Sandal, DS Time = Double Support Time

1[14, 16]

Modified shoes vs Regular shoes:

During the trials conducted with modified and regular shoes, significant fixed biases (p-value < 0.05) in gait speed (0.35 m/sec (three trials average)), stride length (≈ 46 cm), step length (≈ 20 cm (Left), ≈ 33 cm (Right)), hip movement (flexion (≈ 4.2 degree), range (≈ 6 degree)), knee movement (flexion (≈ 1.9 degree), range (≈ 1.66 degree)) and ankle movement (Dorsiflexion (≈1.7 degree), Plantarflexion (≈ 3.3 degree), and range (≈ 3.8 degree)) were observed between Modified shoes and regular shoes (Modified shoes has greater value) (Table 3). Proportional bias was only observed in gait speed and hip range. However, no significant fixed and proportional bias was observed in double-support time. During the trials, a difference in left and right step length (≈ 15 cm) was observed while wearing regular shoes. Whereas, no difference in step length was observed in modified shoes and open-toe sandals.

Table 3: Fixed (mean difference) and Proportional (slop) biases calculated by Bland-Altman analysis between Modified and Regular shoes for spatiotemporal and kinematic parameters (i.e., walking speed, stride length, step length, double support time, hip, knee and ankle movement (right side)). Values with significant bias (P-value < 0.05) are highlighted in bold.

Modified shoes Vs Regular shoes				
Value	**Fixed Bias**	**LoA (U L)**	**95% CI- Bias (P-Value)**	**Slope (P-Value)**
Speed (m/sec)	**0.35**	0.516 0.18	0.3, 0.4 (P-val= 0.0)	**Y = 1.76 *x -1.36 (P-val= 0.0)**
Stride length (cm)	**46.43**	57.65 35.21	43.26, 49.6 (P-val= 0.0)	Y= 0.74 *X -19.84 (P-val= 0.38)
Step length (L) (cm)	**20.16**	22.82 17.50	19.41 , 20.92 (P-val= 0.0)	Y= -0.1 *X 25.05 (P-val= 0.78)
Step length (R) (cm)	**33.23**	38.14 28.32	31.85 34.62 (P-val= 0.0)	Y= 1.32 *X -22.93 (P-val= 0.27)
DS Time (sec)	0	0.02 -0.02	-0.01 , 0.01 (P-val= 0.74)	Y= -0.11 *X 0.03 (P-val= 0.71)
Hip angle (Degree)				
Flexion	**4.24**	5.46, 3.01	3.79, 4.69 (P-val= 0.0)	Y= -0.19 *X+9.3 (P-val= 0.32)
Extension	**0.76**	1.20, 0.31	0.6, 0.92 (P-val= 0.0)	Y= -0.05 *X+ 3.47 (P-val= 0.59)
range	**6**	7.71, 5.28	6.37, 7.63 (P-val= 0.0)	**Y= 0.61 *X -19.64 (P-val= 0.0)**
Knee angle (Degree)				
Flexion	**1.94**	3.92, -0.04	1.22, 2.66 (P-val= 0.0)	Y= -0.0 *X+2.06 (P-val= 0.99)
Extension	0.02	0.309, -0.269	-0.09, 0.13 (P-val= 0.678)	Y= 0.27 *X+3.46 (P-val= 0.2)
range	**1.66**	3.30, 0.02	1.06, 2.26 (P-val= 0.0)	Y= 0.57 *X -0.14 (P-val= 0.3)
Ankle angle (Degree)				
Dorsiflexion	**1.7**	3.60, -0.205	1.0, 2.4 (P-val= 0.0)	Y= 0.15 *X -0.15 (P-val= 0.36)
Plantarflexion	**-3.36**	-2.67, -4.04	-3.61, -3.11 (P-val= 0.0)	Y= 0.01 *X -1.68 (P-val= 0.96)
range	**3.86**	4.57, 3.14	3.6, 4.12 (P-val= 0.0)	Y= -0.13 *X+6.15 (P-val= 0.42)

Abbreviations: LoA (U,L) = Limit of Agreement (Upper , Lower), 95% CI-Bias (P-Value) = 95% confidence interval for bias (P-Value), DS time= Double Support Time, Regression equation for proportional bias : (Y = slop ∗ x ± intercept)

[1]The average value of results obtained over 3 trials (conducted at intervals of 3-4 days)

Modified shoes vs Open-Toe sandal:

Bland-Altman analysis has exhibited significant biases in gait speed (≈ 0.16 m/sec), stride length (≈ 19 cm), step length (≈ 15 cm), hip and ankle range of motion (Table 4). The modified shoes exhibited a greater hip range of motion compared to open-toe sandals (≈ 1.8 degree), whereas the open-toe sandals showed more ankle movement (Dorsiflexion (≈ 1.2 degree), Plantarflexion (≈ 2.2 degree), and range (≈ 2.4 degree)) compared to the modified shoes (Table 4). No significant proportional bias was observed in any of the spatiotemporal and kinematic parameters. No significant fixed and proportional bias was observed in double-support time and Knee movement (Table 4).

Table 4: Fixed (mean difference) and Proportional (slop) biases calculated by Bland-Altman analysis between Modified shoes and Open-Toe sandal for spatiotemporal and kinematic parameters - walking speed, stride length, step length, double support time, hip, knee and ankle movement (right side). Average values with significant bias (P-value < 0.05) are highlighted in bold.

Modified shoes Vs Open-Toe sandal[1]				
Value	**Fixed Bias**	**LoA (U L)**	**95% CI- Bias (P-Value)**	**Slope (P-Value)**
Speed (m/sec)	**0.16**	0.337 -0.021	0.11, 0.21 (P-val= 0.0)	Y 0.07 *X 0.08 (P-val= 0.88)
Stride length (cm)	**19.08**	30.852 7.314	15.76, 22.41 (P-val= 0.0)	Y= -0.47 *X 66.94 (P-val= 0.37
Step length (L) (cm)	**15.49**	18.317 12.66	14.69, 16.29 (P-val= 0.0)	Y= -0.21 *X 26.75 (P-val= 0.55)
Step length (R) (cm)	**15.05**	18.976 11.126	13.94, 16.16 (P-val= 0.0)	Y= 0.16 *X 6.91 (P-val= 0.76)
DS Time (sec)	0	0.041 -0.034	-0.01, 0.01 (P-val= 0.524)	Y= 0.06 *X -0.01 (P-val= 0.95)
Hip angle (Degree)				
Flexion	-0.08	1.216, -1.376	-0.55, 0.39 (P-val= 0.711)	Y= -0.02 *X+0.49 (P-val= 0.84)
Extension	0.14	0.903, -0.623	-0.14, 0.42 (P-val= 0.285)	Y= 0.16 *X+2.24 (P-val= 0.38)
range	**1.8**	3.816, -0.216	1.06, 2.54 (P-val= 0.0)	Y= 0.13 *X+1.93 (P-val= 0.51)
Knee angle (Degree)				
Flexion	0.6	2.439, -1.239	-0.07, 1.27 (P-val= 0.074)	Y= 0.02 *X -0.23 (P-val= 0.83)
Extension	0.12	0.499, -0.259	-0.02, 0.26 (P-val= 0.081)	Y= -0.16 *X+0.58 (P-val= 0.2)
range	0.22	1.771, -1.331	-0.35, 0.79 (P-val= 0.402)	Y= -0.01 *X+2.19 (P-val= 0.94)
Ankle angle (Degree)				
Dorsiflexion	**-1.2**	0.476, -0.556	-1.23, 0.15 (P-val= 0.031)	Y= 0.05 *X -1.43 (P-val= 0.46)
Plantarflexion	**2.2**	2.52, 1.88	2.08, 2.32 (P-val= 0.0)	Y= 0.16 *X+0.42 (P-val= 0.3)
range	**-2.48**	-0.355, -4.605	-3.26, -1.7 (P-val= 0.0)	Y= -0.17 *X-1.71 (P-val= 0.09)

Abbreviations: LoA(U,L) = Limit of Agreement (Upper , Lower), 95% CI-Bias (P-Value) = 95% confidence interval for bias (P-Value), DS time= Double Support Time, Regression equation for proportional bias : (Y = slop ∗ x ± intercept)

1The average value of results obtained over 3 trials (conducted at intervals of 3-4 days)

Discussion:

In the modified shoes trials, significant improvements in spatiotemporal and kinematic parameters were observed when compared to regular shoes and open-toe sandals. Specifically, the parameters obtained with the modified shoes closely aligned with the normal ranges (Reference value) (Table 2) based on the subject's age, gender, BMI, and anthropometric measurements. The primary issue in the regular footwear trials, such as uneven step length and reduced limb range of motion, stemmed from discomfort caused by friction in the toe area and pain in the right thumb. The custom-designed modified shoes, tailored to the subject's foot profile, and open-toe sandals (which has open-toe area) effectively addressed these problems. This resulted in improvements in gait speed, stride length, and even step lengths (Table 2). Excessive ankle pronation could be a significant factor in reduced stride length, step length, lower limb range of motion, and overall gait efficiency [13, 20]. The inverted heel cup in the modified shoes helps counterbalance this excessive pronation [2–5], which contributes to improved gait efficiency and increased lower extremity range of motion. The modified shoes trials showed a clear improvement in spatiotemporal and kinematic parameters compared to the regular shoes and open-toe sandals (Table 3,4). This improvement validates the hypothesis that modified shoes tailored to the subject's foot profile can enhance gait efficiency and lower extremity joint mobility. The modified footwear's ability to better support foot mechanics, particularly by addressing excessive ankle pronation and providing a better fit, directly contributes to these positive changes. In the comparison between modified shoes and open-toe sandals, a greater range of ankle motion was observed in open-toe sandals (Table 4). The primary reason for this difference is the use of a stiffer rubber layer in the modified shoes, which aids in better load distribution and support. A stiffer sole restricts excessive ankle movement [11, 25] and helps improve gait efficiency [12]. Additionally, due to the subject's foot condition, excessive ankle and toe movement can be painful; therefore, the sole has been made stiffer.

Conclusion:
This study presents a low-cost solution—EVA shoes—designed to assist patients with foot deformities. Significantly more affordable than surgeries and traditional custom-made footwear, EVA shoes demonstrate superior adaptability for patient-specific modifications. The findings indicate that modified shoes yields improved spatiotemporal and kinematic parameters compared to regular shoes and open-toe sandals, resulting in enhanced range of motion and gait efficiency. Key modifications, such as the inverted heel cup and stiffer sole, contribute to these benefits. The analysis allows us to reject null hypotheses A and B, confirming that there are significant differences in subjects ambulatory parameters across different footwear conditions and that modified shoes positively influences ambulatory movement by taking it closer to normal range. Moreover, employing a 3D Plexiglas box for measuring foot morphology and POP custom shoes last aids in the efficient preparation of custom shoes. The subjects continued use of modified shoes over the past six months without issues reinforces their effectiveness and encourages further exploration of this innovative approach. Continued research is essential to fully understand the long-term impacts of low-cost custom-made EVA shoes on subjects mobility and comfort.

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Declarations
"The authors declare that they have no known competing financial interests or personal relationships"

Data availability:
Data will be made available on reasonable request

Reference

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