Design and Validation of a Real-Time Visual Feedback System to Improve Minimum Toe Clearance (mTC) in Transfemoral Amputees

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***Abstract*— Tripping is accompanied by reduced minimum toe clearance (mTC) during the swing phase of gait. The risk of fall due to tripping among transfemoral amputees is nearly 67% which is greater than the transtibial amputees. Therefore, intervention to improve mTC can potentially enhance the quality of life among transfemoral amputees. In this paper, we first develop a real-time visual feedback system with center of pressure (CoP) information. Next, we recruited six non-disabled and three transfemoral amputees to investigate the effect on mTC while participants were trained to shift the CoP anteriorly/posteriorly during heel strike. Finally, to assess the lasting effect of training on mTC, retention trials were conducted without feedback. During feedback, posterior shift in the CoP improved the mTC significantly from 4.68 $\pm$ 0.40 cm to 6.12 $\pm$ 0.68 cm ($p < 0.025$) in non-disabled participants. A similar significant improvement in mTC from 4.60 $\pm$ 0.55 cm to 5.62 $\pm$ 0.57 cm was observed in amputees during posterior shift of CoP. Besides mTC, maximal toe clearances, i.e., $maxTC_1$ and $maxTC_2$, also showed a significant increase ($p < 0.025$) during the posterior shift of CoP in both the participants. Moreover, during retention, mTC did not differ significantly ($p > 0.05$) from feedback condition in amputee, suggesting a positive effect of feedback training. The foot-to-ground angle (FGA) at mTC increased significantly ($P < 0.025$) during posterior shift feedback in non-disabled suggests active ankle dorsiflexion in increasing mTC. However, in amputees, FGA at mTC did not differ significantly during both anterior and posterior CoP shift feedback. The present findings suggest CoP feedback as a potential strategy during gait rehabilitation of transfemoral amputees.**

***Index Terms*— Biofeedback, minimum toe clearance, rehabilitation, infra-red sensor, transfemoral amputee.**

I. Introduction

TRIPPING is a major cause of potential falls among lower limb amputees. More than 50% of lower limb prosthetic users fall at least once a year [1]. People with transfemoral amputation fall more frequently than the transtibial amputees, with more than 60% of falls at least once in a year due to tripping [2], [3]. Tripping occurs during the mid-swing phase of gait when the toe approaches minimum distance from the ground, i.e., at minimum toe clearance (mTC) which is defined as the minimum vertical distance between the lowest point under the front part of the foot and the ground, during mid-swing, while the foot progresses forward with maximum swing velocity [4], [5]. Therefore, mTC is an important consideration to quantify the risk of tripping in the lower limb amputee population.

Earlier, it has been demonstrated that in non-disabled individuals, mTC is most sensitive to ankle dorsiflexion (3mm/degree), and thus, mTC can be increased substantially by simply increasing the dorsiflexion angle at the ankle during the mid-swing phase [6]. This approach has been translated to increase toe clearance in a transfemoral prosthesis, where researchers have been primarily focusing on the ankle dorsiflexion to enhance the mTC. The advanced motorized or hydraulic ankle can substantially enhance mTC through angular rotation of the ankle joint during the mid-swing phase [2], [4], [7]. However, these advanced prosthetic designs not only have poor coordination capability between user and prosthesis [8] but are much expensive to be afforded by the people in developing countries. In addition, the majority of prostheses being used, especially in developing countries, are mechanically passive and must be learned to control via socket-limb interaction. The frugal aspect of the passive prosthesis, such as its low cost, local availability, durability, simple to process using local production capabilities, and simple to repair, makes them a popular choice among the amputee population [9]. The ‘Jaipur foot’ organization in India is one such real-life example which is pioneered in manufacturing the highly successful passive prosthesis for poor and lower-middle-class amputee population in India and across the world [10]. The method to enhance mTC in those passive prostheses is by deliberately reducing the prosthesis length compared to the contralateral limb or through adjustment of the knee swing phase flexion resistance of the mechanical knee [11]. However, a significant leg-length discrepancy decreases walking efficiency [12], reduces gait performance, and can lead to low back pain [13], [14] whereas adjusting the knee flexion resistance produces undesirable effects on

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This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the India Ethics Committee, All India Institute of Medical Sciences, New Delhi, under Approval No. IEC-222/04.05.2018.

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gait performance such as limited control over the action of the swing knee, diminished ability to adjust movement and walking speed and prone to occasional perturbations during foot landing [11]. Therefore, a potential strategy to enhance toe clearance is needed, which should be biomechanically appropriate and economically affordable.

The low-cost prostheses incorporating single-axis passive knee joint and solid ankle cushion heel (SACH) foot that can provide adequate toe clearance has been an important goal for quite some time. Here, our goal is to design and implement an intuitive biofeedback environment that is capable of enhancing the toe clearance in transfemoral amputee in a much conducive manner. In the past, motor learning during biofeedback training has shown a positive outcome during gait and balance performance [15], [16]. Visual feedback during gait training has shown a promising effect on various gait mobility outcomes, with significant research focusing on the gait symmetry improvements and balance recovery in amputees and healthy individuals [17] – [19]. Tirosh and Nagano *et al.* have demonstrated a positive effect of real-time visual toe trajectory feedback on the mTC [20], [21] with a significant increase in mTC during feedback compared to without feedback condition in older adults and stroke patients. These studies suggest an active involvement of the lower limb joint angles during the elevation of the toe to match the target toe trajectory with feedback. This strategy may not be a feasible approach for the transfemoral amputee population due to the absence of biological knee and ankle joint movement in the prostheses.

In transfemoral amputees, due to the absence of ankle plantar flexors muscles, reduced propulsion force during late stance (push-off) was generally observed [22]. The increase in the propulsion has been shown to modulate the swing phase kinematics particularly the knee flexion angle in non-disabled and stroke patients [23]– [25] thus altering the toe clearance [26]. Moreover, in amputees, deficit propulsion force is compensated through proximal power redistribution at the residual hip muscles during early and late stance phase (push-off) and accelerate limb into swing phase [27]. A similar compensatory work at hip extensor muscle during early stance shown to enhance the prosthetic propulsion force in response to increased demand of walking speed [28], [29]. Therefore, we believe that swing phase angles can be altered to influence the toe clearance in amputees owing to the increased underlying propulsion force and intact residual hip power in amputees.

The distance between center of mass (CoM) and center of pressure (CoP) (CoM-CoP) at heel strike plays important role in generating the forward propulsion of the CoM [30]. The CoP acting on the plantar surface of the foot with reference to the lower limb joint center changes the moment arm of the ground reaction force vector, thereby influencing the lower limb joint moments [31]– [33]. Due to the rigid ankle joint of the SACH foot and mechanical knee being in extended position at heel strike, different orientation of the shank (pylon in the prostheses) with the laboratory vertical axis influences the location of the CoP at heel strike [31] thereby influencing the joint moment during stance phase. Moreover, with an increase in the shank angle with vertical, CoP shifts posteriorly at heel strike and vice-versa [31]. A posterior CoP shift at heel strike increases the shank angle with vertical and requires the heel to be placed farther away from the body's CoM, thus increasing the distance between CoM-CoP at heel strike [34]. As the distance between CoM-CoP at heel strike increases (also increases the step length), this allows the amputee to increase residual hip extensor moment during early stance to counteract the increased knee flexion moment due to body weight [35]. This increased residual hip extensor work during early stance moves body's CoM forward with enhanced momentum, thus increasing the distance and angle between the prosthetic trailing limb CoM-CoP at toe-off and prolonging the entire stance phase. This may also allow the CoP to travel front part of the foot (which otherwise is restricted in the rear foot and travels front foot for a very short duration to extend the double limb support for prosthetic knee stability [36]) while the dynamic elasticity of the front part of the SACH foot allows the foot to compress and recoil during push-off. The relation of modulation in the CoM-CoP distance at heel strike and toe-off has been observed in the older adult population for whom tripping is the major problem due to weak ankle power [37]. Moreover, this increased angle between CoM-CoP at toe-off (also known as trailing limb angle (TLA)) may contributes to the enhanced propulsion force during late stance [38]– [40] in transfemoral amputees.

Therefore, we hypothesized that shifting the COP posteriorly at heel strike would increase the toe clearance in transfemoral amputees with SACH foot owing to the increase in the underlying propulsion force and the extra work at the residual hip extensor muscles. On the contrary, an opposite effect would be observed with anterior CoP shift at heel strike, i.e., decrease in the toe clearance. Our objective in this study is twofold, firstly to design and implement a real-time visual feedback system to train participants for moving the CoP anterior/posterior while heel striking, and second to observe the effectiveness of such training during retention. Additional variables like Foot-to-ground angle are also recorded simultaneously to critically discuss the outcomes of the proposed study. The following paper is organized into four different sections. The section I provides the introduction about the work, section II describes methods and material regarding the design and implementation of biofeedback environment, section III presents the results and finally, section IV provides the discussion of the study.

II. Material and Methods

A. Feedback Environment Setup

The feedback system consists of 1) Instrumented shoe – to measure real-time toe clearance and foot-to-ground angle (FGA); 2) Pressure insole – to measure the real-time center of pressure (CoP); 3) Monitor screen – to display real-time visual CoP feedback; and 4) a standard treadmill for walking. The instrumented shoe was developed in the laboratory that incorporates four infra-red distance sensors (from Sharp Corporation, Japan) anatomically located on the lateral side of the shoe as shown in fig. 1(a). Toe clearance measured

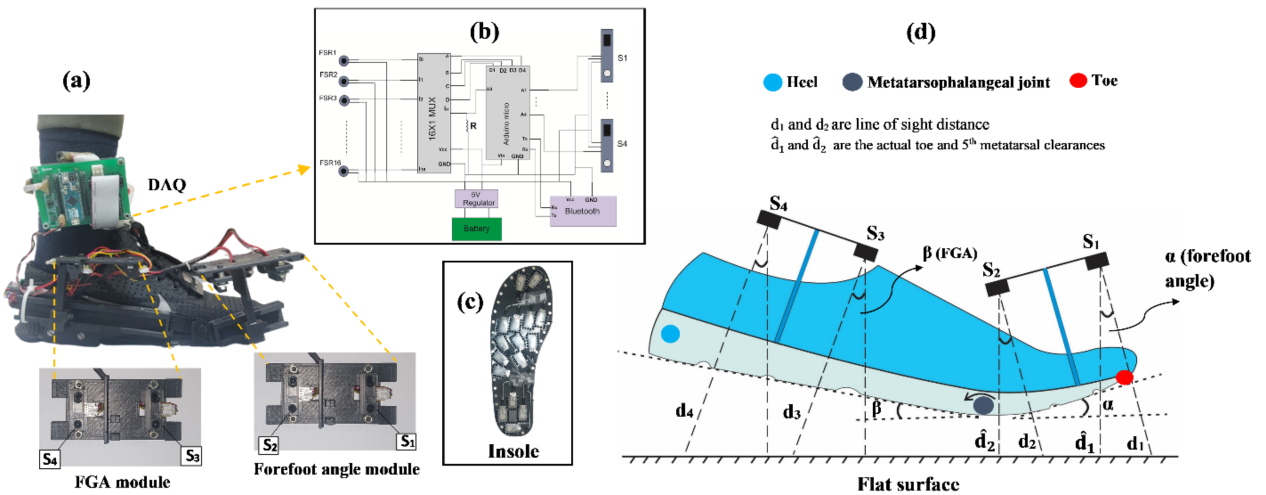

Fig. 1. Instrumentation setup. (a) - Sagittal view of an actual prototype of the instrumented shoe showing forefoot angle module on the rear part of the shoe, foot-to-ground angle (FGA) module at the middle of the shoe, and data acquisition unit (DAQ) at the ankle position. (b) – Schematics of the internal circuit diagram of the DAQ unit. (c) –Top view of pressure insole incorporating sixteen FSR sensors (d) – Sagittal schematic view of the instrumented shoe showing the location and distances measured by the IR sensors.

by previous approaches such as 3D camera-based and IMU-based motion capture system is merely the estimation of toe clearance involving the assumption that the foot is a rigid model from heel to toe [41]– [44]. However, in practice, the rigid model assumption is not valid and may introduce an error in toe clearance measurement due to angular movement of the forefoot w.r.t the rear foot at the metatarsophalangeal joint as shown in fig. 1(d). Therefore, the consideration of the forefoot angle is important in the accurate measurement of the toe clearance during the swing phase of the gait cycle. Here, an accurate measure of toe clearance is performed via a pair of IR sensors (S_1 and S_2) placed on the front part of the shoe, i.e., between the metatarsophalangeal joint and the toe location to calculate the forefoot angle (α), as shown in fig. 1(a). IR sensors (model no. GP2Y0A41SK0F, from Sharp Corporation, JAPAN) with a measurement range of 4 cm to 30 cm were used to measure toe clearance, as the toe clearance lies within those ranges [45], [46]. The accurate toe clearance was obtained by multiplying the line-of-sight distance provided by the sensor with the cosine of forefoot angle (α). A basic trigonometric approach was used to calculate the forefoot angle (α). Line of sight distances d_1 and d_2 from the pair of sensors (S_1 and S_2 respectively) (as shown in fig. 1(d)) were utilized to calculate α from equation (1) and (2)

$$(d_1 - d_2) \times \cos(\alpha) = \mathrm{L} \times \sin(\alpha) \tag{1}$$

$$\alpha = \tan^{-1}(\frac{d_1 - d_2}{L}) \tag{2}$$

where L is the distance measured between the fixed locations of the sensor in the angle module. According to fig. 1(d), d_1, d_2 is the line-of-sight distance provided by the sensor, whereas vertical distances $\hat{d}_1 = d_1 \times \cos(\alpha)$ and $\hat{d}_2 = d_2 \times \cos(\alpha)$ is the true toe and 5th metatarsal clearances.

Beside toe clearance, foot-to-ground angle (FGA), which is the angle of the rearfoot with respect to the ground, was also calculated using a similar approach as used to calculated α by employing a pair IR sensor (S_3 and S_4) on the rear part of the shoe between the heel and the 5th metatarsal position as shown in fig. 1(d)

$$\beta = \tan^{-1}(\frac{d_3 - d_4}{L}) \tag{3}$$

where L is the distance measured between the fixed locations of the sensor in the FGA angle module and line of sight distances d_3 and d_4 from the pair of sensors (S_3 and S_4 respectively) (as shown in fig. 1(d)) were utilized to calculate β from equation (3). The practicability of this developed instrumented shoe in gait events detection in a real-life scenario [37] and in the classification of the locomotion modes [38] has been demonstrated by us. Detailed hardware and algorithm information for developing the instrumented shoe can be found elsewhere [47], [48]. The indigenously developed pressure insole incorporating sixteen force resistive sensors (A301, from Tekscan, USA), as shown in fig. 1 (c), was used to measure the center of pressure (CoP) in the sagittal plane. The sagittal CoP was calculated, as the average of the force measured by the sensors weighted with corresponding sensors coordinates, using equation (4).

$$\mathrm{CoP} = \frac{\sum_{i=1}^{n} \mathrm{F_i Y_i}}{\sum_{i=1}^{n} \mathrm{F_i}} \tag{4}$$

where, CoP is the instantaneous position of the CoP along sagittal plane with reference to the origin assigned to the insole, $\mathrm{F_i}$ is the force measured by $\mathrm{i_{th}}$ sensor, $\mathrm{Y_i}$ are the sagittal coordinates of the center of the $\mathrm{i_{th}}$ sensor in the insole with reference to the insole origin (situated at bottom right of the insole) and n is the total number of sensors in the insole. The insole design, development, and validation of the insole are described in our previous study [49].

A single data acquisition system (DAQ) simultaneously acquires the data from the insole and instrumented shoe. The DAQ consists of an Arduino micro, a 16 × 1 multiplexer (CD4067BE), a 5V voltage regulator, a voltage divider circuit,

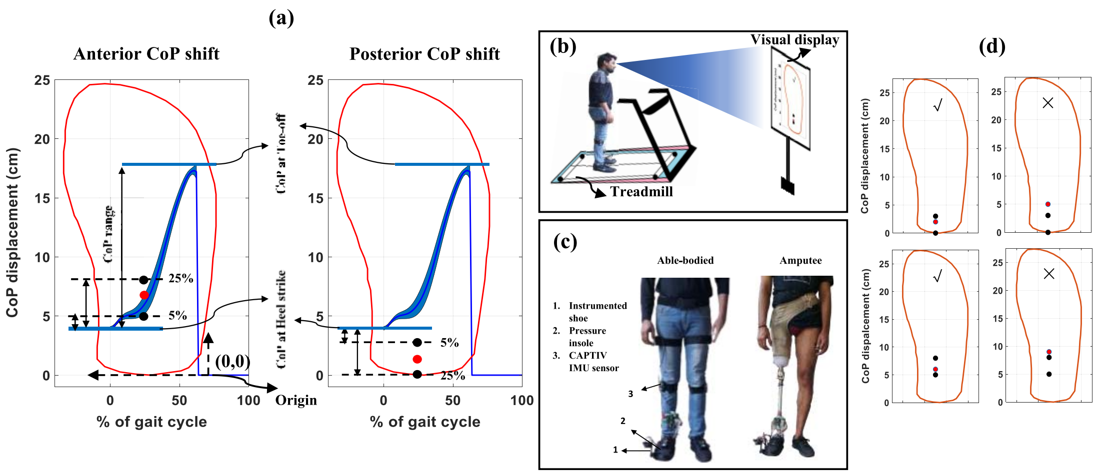

Fig. 2. Feedback protocols and experimental setup. (a) -The location of the black points at 5% and 25% (of the average baseline CoP range) anterior and posterior to the average baseline CoP at heel strike for anterior and posterior CoP shift feedback. The difference between toe-off and heel strike is the CoP range. (b)- A representative visual feedback system for the participants. (c) – A representative non-disabled and amputee subject equipped with 1) Instrumented shoe, 2) pressure insole, 3) CAPTIV IMU sensor. (d) -Visual representation of the center of pressure feedback interface on the monitor screen seen by the participants (correct target corresponds to posterior CoP shift feedback-left top; correct target corresponds to anterior CoP shift feedback-left bottom; the wrong target corresponds to posterior CoP shift feedback-right top; correct target corresponds to anterior CoP shift feedback-right bottom).

an Adafruit Bluetooth module (Bluefruit EZ-Link), and a Li-Po 800mAh rechargeable battery. The schematics of the circuit diagram is as shown in fig. 1(b). The DAQ unit transmits data wirelessly to the remotely located computer at a sampling rate of 45Hz. In addition, the CoP data was also acquired simultaneously using high-speed USB data cable for the purpose of a real-time CoP visual feedback display. The data through USB was preferred to avoid any delay in CoP feedback translation on the monitor screen, which was partially observed during wireless data communication. The customized MATLAB (R2020a, MathWorks, USA, academic license) script was developed for visual display and projection of CoP displacement (as a point) on the screen (HP, 32-inch IPS Panel, resolution (1920 × 1080 pixels)).

B. Participants Details

Data collection from six young non-disabled and three trans-femoral amputee male participants were carried out during the experiment. Non-disabled subjects were examined before the recruitment and had no neurological, musculoskeletal or any ambulatory dysfunction. The prosthesis worn by each amputee participants for the experimental trial was the same and none of the amputees had any other medical conditions that could affect the walking performance during the experiment. All amputee prostheses featured mechanically passive single axis knee joint (locally manufactured in India) and SACH foot. A flexible quadrilateral socket made of thermoplastic polypropylene polymer sheet was equipped with each prosthesis which is fitted to the residual limb using suction system. No pain or walking instability (walked independently without any support) with the prostheses was reported during activity of daily living. Prior to the participation, all the participants were asked to sign consent form giving approval of voluntary participation in the experiment. This study was approved by the All India Institute of Medical Sciences (AIIMS), New Delhi, India ethics committee (Ref. no IEC-222/04.05.2018).

C. Experiment Protocols

The participants were equipped with the instrumented shoe, the pressure insole, and CAPTIV IMU sensors on the right foot, as shown in fig. 2 (c). The DAQ unit for IR sensors and insole was attached at the ankle position using a Velcro strap. A 3D motion capture system (from CAPTIV motion, TEA ergo Inc., France), recorded the simultaneous measurements of toe clearance for verification purposes. CAPTIV uses multiple inertial measurement units (IMUs) attached to the body as per the standard protocol to measure full-body kinematics, including toe clearance [50], [51]. Based on the similar foot size (foot length; 22±1.3cm for non-disabled and 21.3±0cm for amputees) of the participants, only one size of the instrumented shoe (UK8) was utilized. No participants reported any inconvenience with the UK8 size during data collection. The experiment was conducted for three different walking sessions, i.e., baseline, feedback (anterior/posterior excursion of CoP), and retention. Two session of treadmill acclimatization of 5min each was conducted for both amputee and the non-disabled participants prior to data collection. Meanwhile, the preferred walking speed of the participants was adjusted on the treadmill by taking continuous verbal input from the participants. Each walking session consists of five trials where each trial lasted for 40 seconds. During the baseline session, participants were asked to walk on the treadmill; *no visual feedback of CoP was provided.* The CoP and the instrumented shoe data acquired during the baseline session were used to compare the data acquired during the feedback and retention session. The feedback session comprises of two different walking conditions corresponding to two different feedback types, i.e., posterior CoP shift feedback (FedPostCoP) and anterior CoP shift feedback (FedAntCoP). The details of training protocols are mentioned following.

D. Training Protocols

1) Baseline: During baseline walking, the participants walked without CoP feedback. The CoP value at heel strike and toe-off was recorded and averaged across the trials for each participant. The differences between these averages were further considered as the average baseline CoP range as shown in fig. 2(a).

2) Anterior Feedback: During FedAntCoP, participants were instructed to shift their CoP at heel strike between two black points lying at 5% and 25% (of the average baseline CoP range) anterior to the average baseline CoP at heel strike as shown in fig. 2(a) left side. The 5% and 25% were decided based on the maximum voluntary CoP shift performed by the participants during acclimatization.

3) Posterior Feedback: During FedPostCoP, participants were instructed to shift their CoP at heel strike between two black points (correspond to the minimum and maximum boundary of the target zone (range)) lying at 5% and 25% (of the average baseline CoP range) posterior to the average baseline CoP at heel strike as shown in fig. 2(a) right side. The position of black points at 5% and 25% represent the minimum and maximum bound within which the CoP must lie during feedback without compromising the gait stability of the participants. The CoP shift was translated to visuals in real-time to the screen placed in front of the subject's line of sight, at an approximate distance of 1.5m, through a meaningful visual representation, generated using a MATLAB script, as shown in fig. 2(b). Visual representation describes a 2D foot outline that incorporates a red pointer (mapped to the CoP value) which moves according to the CoP displacement. During the stance phase, the red pointer typically moves from the heel to toe position. The pointer disappears from the screen during the swing phase as there is no vertical ground reaction force available for the foot while the foot is in the air. A familiarization session was conducted before the feedback session. Participants were encouraged and motivated to target the red pointer between two black points (as shown in fig. 2(a)) at heel strike while walking. A tick ($\surd$) was presented to the participants when they placed the red dot correctly between the black points (fig. 2(d) left side). Similarly, a cross (X) was displayed on the screen, which corresponds to the wrong target position of the red point on the screen (fig. 2(d), right side). After the feedback session, a final session of retention was conducted. 15 minutes of the break was given between feedback and retention session. The retention session quantifies the effect of feedback training on the enhancement of toe clearance outcomes when the visual feedback is absent. During retention, when the visual feedback was absent, the participants were asked to walk for another two trials (40 seconds each) during two different feedback conditions - an anterior shift of CoP (RetAntCoP) and posterior shift of CoP (RetPostCoP). The instruction for the anterior and posterior shift was randomized in the retention session by the experimenter.

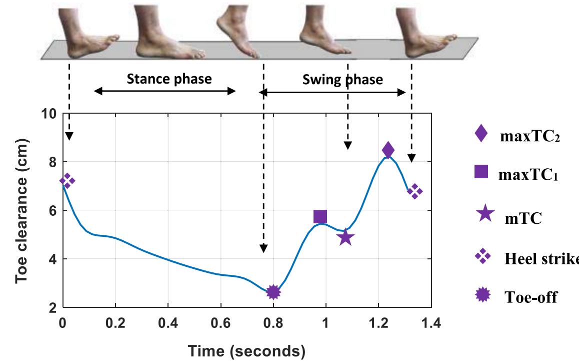

Fig. 3. A representative toe clearance trajectory in a single gait cycle.

E. Data Analysis

1) Toe Clearance: Besides mTC, the other important toe clearance parameters are the first maximum toe clearance ($maxTC_1$) and the second maximum toe clearance ($maxTC_2$), which are also referred to as trail and lead toe clearance in literature [52] as they appear before and after the mTC as shown in the fig. 3. The $maxTC_1$ and $maxTC_2$ have been shown as good estimators of the risk of tripping while negotiating the obstacles [52]. Due to the absence of the ankle dorsiflexion and plantarflexion movement at ankle joint in mechanically passive prosthesis, the foot-to-ground angle (FGA) may be a more meaningful descriptor to partially explain the effect of restricted movement of ankle joint on the overall toe clearance.

The analysis was done in an offline mode, post data acquisition, using MATLAB 2021a (MathWorks, USA) software. The block diagram shown in fig. 4, depicts the overall signal processing and parameter estimation process. The toe clearance and FGA were acquired and filtered using a 5^{th} order zero-phase Butterworth low pass filter. It is a common practice to normalize the CoP data to participants foot length before the CoP data analysis. But here, it should be noted that the CoP displacement data along sagittal plane was not normalized to each participant's foot length owing to the similar foot length (22±1.3cm) of non-disabled participants and amputees SACH foot length (21.3±0cm).

A vertical ground reaction force (vGRF) is defined as the arithmetic summation of all the sixteen force (in Newton (N)) values from the FSRs in the insole. The gait event i.e., heel strike (HS) and toe-off (TO) were detected from CoP and vGRF data using previous approach [53]. Using time series CoP(k) signal and time series vGRF(k) signal as an input, the gait event index was computed based on the simple threshold rule.

$$\mathrm{CoP(k)} = \mathrm{NaN} \forall \mathrm{k} | \mathrm{vGRF(k)} < 10\mathrm{N}$$
$$\mathrm{CoP_{FF}} = \frac{CoP_{max} + CoP_{min}}{2}$$
$$\mathrm{HS} = \mathrm{i}| \begin{Bmatrix} \mathrm{CoP(i-1)} = \mathrm{NaN} \\ \mathrm{CoP(i)} = \mathrm{CoP_{FF}} \end{Bmatrix};$$
$$\mathrm{TO} = \mathrm{i}| \begin{Bmatrix} \mathrm{CoP(i-1)} = \mathrm{CoP_{FF}} \\ \mathrm{CoP(i)} = \mathrm{NaN} \end{Bmatrix}$$

where, CoP_{max} and CoP_{min} are the maximum, and minimum values of the CoP averaged across the trials.

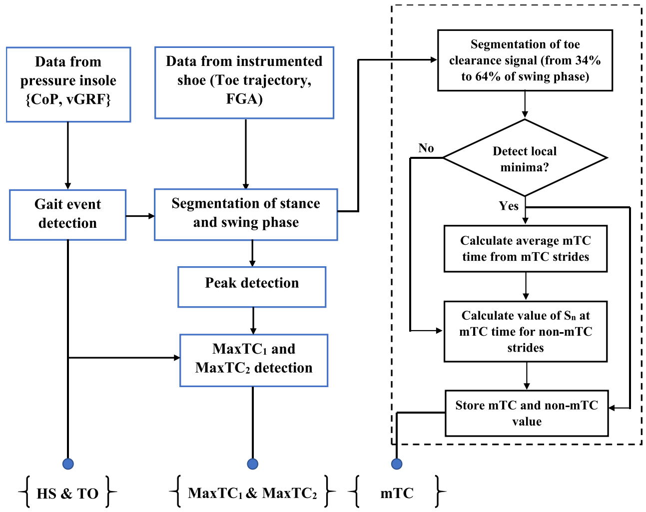

Fig. 4. Flowchart of the data processing and the outcome parameter estimation scheme. HS and TO refer to Heel Strike and Toe Off, respectively.

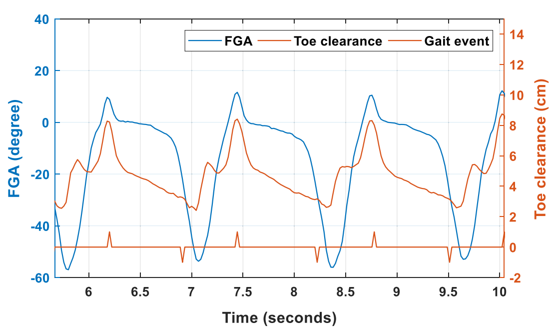

Fig. 5. A representative toe clearance (red color) and Foot-to-ground angle (blue color) where, positive valued red color impulse signal corresponds to heel strike and negative valued corresponds to toe-off events.

Subsequently, toe clearance and FGA were segmented into the stance and swing phase based on gait events, as shown in fig 5.

In general, mTC is characterized as a local minimum during mid-swing phase of the gait cycle [4]. However, it was observed that local minima were absent in many cases, pl. refer to fig.10, as reported in previous literature as well [54]–[56]. However, since a local minimum is required as the common measure outcomes of mTC, therefore, it is important to be able to quantify foot clearance in cases where a local minimum of toe height does not exist. Therefore, two different mTC identification strategies were adopted to determine the value of mTC in strides with and without local minima. mTC was identified as a local minimum in the swing phase, which generally occurs during 34% to 64% of the swing phase segment [2]. To calculate toe clearance in strides without local minima, the following steps were observed – 1) the time of occurrence of mTC from the toe-off was extracted from the strides having mTC events 2) and then the toe height at mean mTC time from the toe-off for non-mTC strides (strides without local minima) provides the non-mTC value. maxTC_1 was identified as the local maximum between the toe-off and the mTC, whereas the maxTC_2 was identified as the local maximum between the mTC and the heel strike. Finally, the FGA was recorded at mTC (i.e., FGA_{mTC}), heel strike (i.e., FGA_{HS}), and toe-off (i.e., FGA_{TO}) for further analysis.

2) Statistical Analysis: The data were checked for normality before conducting an analysis of variance (ANOVA) test. One-way repeated measure ANOVA was conducted to observe any significant difference in the average anterior and posterior shift in CoP compared to the average baseline CoP. Tukey's multiple comparison test was conducted to compare pair group means. ANOVA was also conducted to observe any significant effect of CoP feedback on various outcome measures, namely mTC, maxTC_1, maxTC_2, FGA_{mTC}, FGA_{HS}, FGA_{TO}. A correction factor to the alpha-value was used by normalizing the alpha value by the number of comparisons. The two comparisons (baseline V/S FedPostCoP and baseline V/S FedAntCoP) for each variable (i.e., mTC, maxTC_1, maxTC_2, FGA_{mTC}, FGA_{HS}, FGA_{TO}) led to a new alpha value (alpha $= 0.05/2 = 0.025$). The results were considered significant based on the new alpha value. For each type of feedback condition, a paired t-test was conducted to conclude the effect of visual feedback during retention. The significance level was set to 0.05 $\alpha = 0.05$) for paired t-test before conducting the statistical tests.

III. Results

The demographic details of non-disabled (Age (years): 25.8±3.06; Height (cm): 169.3±2.65; Weight (kg): 71.3±4.32) and transfemoral amputee male participants (Age (years): 28±3.6; Height (cm): 162±5.03; Weight (kg): 71.3±5.85) were noted prior to the experiment. A walking trial of 40 seconds duration consisted of a different number of strides depending on the participant's walking speed (2.2±0.35 km/hr for non-disabled and 1.6±0.48 km/hr for amputee participants) and stride length. Therefore, for analysis, only 25 strides/trial were included from each data collection session, i.e., baseline, feedback, and retention for all the participants. This also excludes few initial and final strides from each trial to avoid any accelerating or deaccelerating effects within the data. Finally, a total of 125 strides from five trials of baseline and feedback were utilized for analysis. A total of 50 strides of retention for all the participants were observed for further analysis.

A. Center of Pressure (CoP) Analysis

Fig. 6(a) shows a representative sagittal CoP trajectory (mean (solid blue line) and standard deviation (shaded region) for single representative non-disabled participants during baseline (left), FedAntCoP (middle) and FedPostCoP (right) as a percentage of gait cycle. The spatial distribution of CoP over the complete gait cycle shows that CoP travels from heel-to-toe direction during the stance phase and becomes zero (flat) during the swing phase of gait. The CoP typically traverses from 4cm at heel strike to 18cm at toe-off during baseline and FedPostCoP walking conditions. Moreover, during FedAntCoP, CoP starts more anteriorly from 8cm at heel strike and traverses till 18cm at toe-off. The average

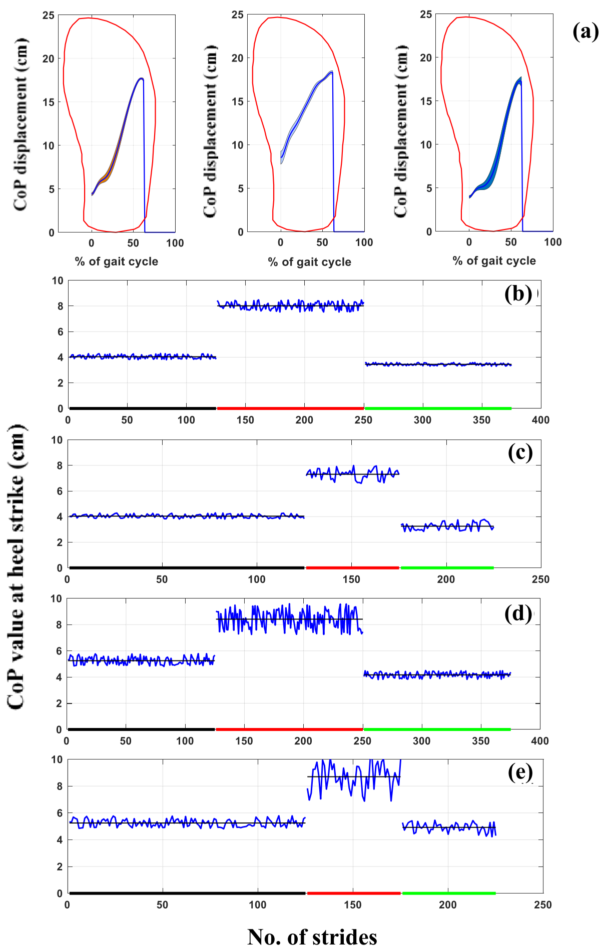

Fig. 6. CoP depiction from non-disabled and amputee participants. (a)- Representative CoP trajectories from non-disabled participants during different conditions – Baseline (left), FedAntCoP (middle) and FedPostCoP (right). CoP values from (b) -Non-disabled during feedback. (c) -Non-disabled during retention. (d)- Amputee during feedback for baseline. (e)-Amputee during retention for baseline (——), FedAntCoP (——), FedPostCoP (——). FedAntCoP: CoP anterior shift feedback, FedPostCoP: CoP posterior shift feedback, RetAntCoP: CoP anterior shift retention, RetPostCoP: CoP posterior shift retention.

CoP values at heel strike across all non-disabled participant (fig. 6(b) corresponds to feedback, fig. 6(c) corresponds to retention) and across all amputee participant (6(d) corresponds to feedback, fig. 6(e) corresponds to retention), during baseline (——), FedAntCoP (——) and FedPostCoP (——) conditions is shown in figure 6(b-e). The CoP shift during feedback conditions indicates the difference in the CoP values at baseline and the feedback condition. As shown in fig. 6(b), the CoP shift for non-disabled participants during FedPostCoP was 0.65±.012cm which was significantly less ($p<0.05$) than the shift during FedAntCoP i.e., 3.85±0.56cm. Despite the small shift in the CoP observed during FedPostCoP, the CoP shift sensitivity is almost equal to the sensitivity during the FedAntCoP condition. This is because of small range of allowable CoP fluctuation (baseline CoP (∼4cm) to CoP at rearest point of heel (∼0cm)) during FedPostCoP compared to FedAntCoP (baseline CoP (∼4cm) to CoP at toe-off (∼18cm)). Moreover, during the retention (fig. 6(c)), the CoP shift further decrement to 0.33±0.21cm for RetPostCoP whereas, during the RetAntCoP, the CoP shift was 3.42±0.72cm. The average CoP during FedPostCoP and FedAntCoP was significantly different ($p<0.05$) from the baseline walking conditions. In amputee (fig. 6(d)), the shift in the CoP during FedPostCoP was 1.1±0.69cm. Moreover, during the FedAntCoP, the average shift in CoP was 2.8±1.32cm. During retention (fig. 6(e)), the margin of shift in CoP was0.41±0.63cm for RetPostCoP which was significantly less ($p<0.05$) than the corresponding FedPostCoP whereas, during RetAntCoP, the CoP margin of shift was 3.89±2.3cm, which was not significantly large compared to the corresponding feedback condition i.e., FedAntCoP ($p>0.05$). In amputee, the average CoP during FedPostCoP and FedAntCoP was significantly different ($p<0.05$) from the baseline walking conditions. Moreover, the CoP shift (with reference to baseline) for both anterior and posterior was higher in non-disabled as compared to amputees.

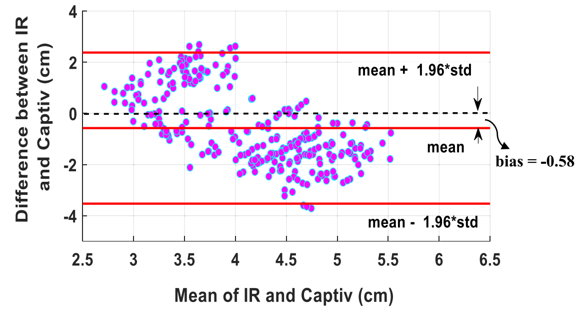

Fig. 7. Agreement in measurement between IR sensor and CAPTIV system approach for mTC estimation; More than 95% of data was observed to be within the 95% limits of agreement [2.3cm to −3.5cm].

B. Agreement of Instrumented Shoe to CAPTIV System

Fig. 7 shows the Bland–Altman plot for mTC obtained with proposed IR-based instrumented shoe against the reference CAPTIV system. The limit of the 95% confidence interval (±1.96SD) around perfect agreement is shown to visualize the limit of agreement. More than 95% of data was observed to be within the 95% limits of agreement [2.3cm to −3.5cm]. Overall, a good agreement between IR sensing and CAPTIV sensing was observed for the collected data.

C. Feedback

Table I provides the statistical analysis of various outcome measures (mTC, $maxTC_1$, $maxTC_2$, FGA_{mTC}, FGA_{HS}, FGA_{TO}) across all the participants separately for non-disabled and amputees for various walking conditions, i.e., baseline, feedback, and retention.

As hypothesized, mTC increased significantly ($p<0.025$) from 4.68±0.40cm during baseline walking to 6.12±0.68cm during FedPostCoP in non-disabled participants. Similarly, in amputees, mTC significantly ($p<0.025$) improved from 4.60±0.55cm during baseline walking to 5.20±0.53cm during FedPostCoP. During FedAntCoP, in amputee, a nonsignificant decrease in mTC compared to baseline was observed. In contrast, during FedAntCoP, a nonsignificant increase ($p>0.025$) in mTC compared to baseline walking was observed in non-disabled participants. During FedPostCoP, $maxTC_1$ increased

TABLE I

MEAN AND STANDARD DEVIATION (SD) OF VARIOUS OUTCOME MEASURES (mTC, maxTC$_1$, maxTC$_2$, FGA$_{mTC}$, FGA$_{HS}$, FGA$_{TO}$) ACROSS DIFFERENT WALKING CONDITIONS FOR NON-DISABLED AND AMPUTEE PARTICIPANTS. ANT.: ANTERIOR; POST.: POSTERIOR

			Able-bodied		P value	Amputee		P value
			Mean	SD		Mean	SD	
mTC (cm)	Baseline		4.68	0.40	-	4.60	0.55	-
	Feedback	Ant.	5.01	0.46	<0.001	4.54	0.41	0.34
		Post.	6.12	0.68	<0.001	5.62	0.57	<0.001
	Retention	Ant.	4.92	0.78	0.19	4.32	0.32	0.15
		Post.	5.69	0.52	<0.001	5.12	0.72	0.08
maxTC$_1$ (cm)	Baseline		5.52	0.38	-	5.94	0.62	-
	Feedback	Ant.	6.27	0.49	<0.001	4.96	0.41	<0.001
		Post.	6.47	0.65	<0.001	6.74	0.53	<0.001
	Retention	Ant.	5.80	0.56	<0.001	4.59	1.20	0.07
		Post.	6.23	0.48	<0.01	6.32	0.26	<0.01
maxTC$_2$ (cm)	Baseline		7.89	0.76	-	8.67	0.72	-
	Feedback	Ant.	5.79	0.68	<0.001	5.55	0.58	<0.001
		Post.	10.78	0.98	<0.001	9.97	0.58	<0.001
	Retention	Ant.	6.56	1.12	<0.001	5.19	0.45	<0.01
		Post.	10.56	1.56	0.12	9.53	0.98	0.21
FGA$_{mTC}$ (degree)	Baseline		-16.20	3.63	-	-19.55	3.0	-
	Feedback	Ant.	-16.35	4.42	0.48	-19.48	2.8	0.51
		Post.	-18.77	4.98	<0.001	-19.57	4.99	0.25
	Retention	Ant.	-15.23	5.12	<0.01	-21.56	2.10	<0.001
		Post.	-17.41	2.3	<0.001	-19.35	4.50	0.32
FGA$_{HS}$ (degree)	Baseline		10.37	3.35	-	12.54	2.81	-
	Feedback	Ant.	0.36	2.80	<0.001	0.40	2.34	<0.001
		Post.	27.14	7.38	<0.001	20.87	3.49	<0.001
	Retention	Ant.	0.89	3.66	<0.01	1.20	2.32	<0.001
		Post.	25.23	8.98	<0.01	18.95	2.56	<0.001
FGA$_{TO}$ (degree)	Baseline		-23.39	2.86	-	-16.53	2.12	-
	Feedback	Ant.	-29.81	3.63	<0.001	-16.98	1.68	0.36
		Post.	-24.63	4.73	<0.001	-15.11	3.11	<0.01
	Retention	Ant.	-25.23	2.69	<0.001	-15.32	2.58	<0.01
		Post.	-24.12	5.57	0.23	-14.32	3.57	<0.001

significantly ($p<0.025$) in non-disabled and amputee participants compared to baseline walking. During FedAntCoP, maxTC$_1$ increased significantly ($p<0.025$) in non-disabled whereas decreased significantly ($p<0.025$) for amputee participants compared to baseline walking. During FedPostCoP, maxTC$_2$ significantly increased ($p<0.025$) whereas during FedAntCoP maxTC$_2$ significantly decreased ($p<0.025$) in both non-disabled and amputees. In summary, the overall toe clearance outcome measures, i.e., mTC, maxTC$_1$ and maxTC$_2$ increased significantly during FedPostCoP compared to the baseline walking. To compare the toe clearance during various walking conditions, i.e., baseline and feedback (FedPostCoP, and FedAntCoP), a representative mean and standard deviation of toe clearance from single non-disabled and amputee participant is shown in fig. 8(a) and 8(b) respectively. During FedPostCoP, throughout the gait cycle, the toe clearance increased compared to the baseline in non-disabled participant (fig. 8(a)) whereas, in amputee participant (fig. 8(b)), the toe clearance increased throughout the gait cycle except during the terminal swing phase where toe clearance is comparable to the baseline condition.

A representative mean and standard deviation of foot-to-ground angle (FGA) from single non-disabled and amputee participants shown in fig. 9(a) and 9(b), respectively. The FGA$_{mTC}$ during FedPostCoP increased significantly ($p<0.025$) whereas, it did not differ significantly ($p>0.025$) during FedAntCoP (Table I) compared to the baseline condition. An increased FGA$_{mTC}$ during FedPostCoP indicates an active ankle plantarflexion; therefore, an active knee or hip flexion at mTC may have contributed to increased mTC during FedPostCoP. However, in amputees, FGA$_{mTC}$ did not differ significantly during different feedback conditions (FedAntCoP and FedPostCoP) compared to the baseline (Table II), suggesting possible contribution in mTC improvement during FedPostCoP either from increased knee or pelvic flexion compared to baseline. The FGA$_{HS}$ was positive (as shown in fig. 9(a), in orientation 1) and increased significantly ($p<0.025$) during FedPostCoP, whereas it decreased significantly ($p<0.025$) nearly to zero i.e., flat foot during the FedAntCoP for both non-disabled and amputee participants. A significant increase in FGA$_{HS}$ represents a higher angle in orientation 1, which may be required to shift the CoP more posteriorly during FedPostCoP, whereas a significant decrease in the CoP to almost flat foot position might be required to shift the CoP more anteriorly during the FedAntCoP. This also justifies the fact that toe clearance at heel strike during FedPostCoP has the highest value followed by baseline and lowest value for the FedAntCoP conditions (fig. 8(a)). The FGA$_{TO}$ was negative in orientation 2 and increased significantly ($p<0.025$) during FedPostCoP in non-disabled but decreased significantly ($p<0.025$) in amputee participants. During FedAntCoP, the FGA$_{TO}$ increased significantly ($P<0.025$) in non-disabled and did not differ in amputee participants.

D. Retention

To investigate the effect of the training on outcome measures, the variables were compared between feedback and corresponding retention conditions. The mTC during retention did not differ significantly ($p>0.05$) from the corresponding feedback condition for amputee participants. However, in non-disabled participants, the mTC differ significantly ($p<0.05$) during RetPostCoP compared to corresponding feedback condition (FedPostCoP). But still, a positive effect of feedback training can be seen during retention as mTC increased by at least 1cm compared to the baseline walking, i.e., from 4.68±0.4cm to 5.69±0.52cm. Moreover, during RetAntCoP, the mTC did not differ significantly ($p>0.05$) from the corresponding feedback condition. The maxTC$_1$ differ significantly ($p<0.05$) for RetPostCoP and RetAntCoP compared with corresponding feedback conditions in non-disabled participants whereas in amputee, the maxTC$_1$ during RetAntCoP did not differ significantly ($p>0.05$) but differ significantly ($p<0.05$) for the RetPostCoP. The maxTC$_2$ did not differ significantly ($p>0.05$) for the RetPostCoP for both the participants but differ significantly ($p<0.05$) for RetAntCoP for both the participants. The FGAmTC differ significantly ($p<0.05$) for the RetAntCoP for both the participants, whereas during the RetPostCoP, FGA$_{mTC}$ differ significantly ($p<0.05$) for non-disabled participants but did not differ significantly ($p>0.05$) for the amputee participants.

The FGA$_{HS}$ differ significantly ($p<0.05$) during RetPostCoP and RetAntCoP for both the participants. The FGA$_{TO}$

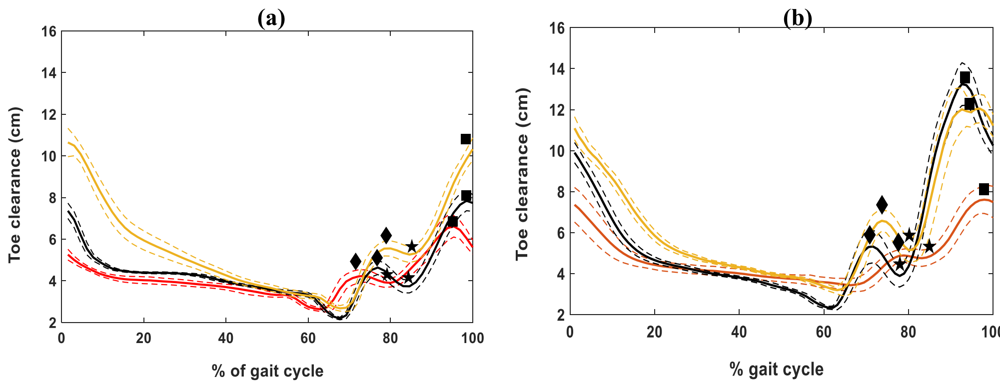

Fig. 8. Toe clearance of a representative participant for three different walking conditions: baseline (——), FedAntCoP (——), FedPostCoP (——) where, dotted line represents the standard deviation and solid line represents the average value. ★ represents mTC, ♦ represents $maxTC_1$ ■ represents $maxTC_2$. (a)- A representative toe clearance from non-disabled participants as a percentage of the gait cycle. (b) -A representative toe clearance from amputee participant as a percentage of the gait cycle.

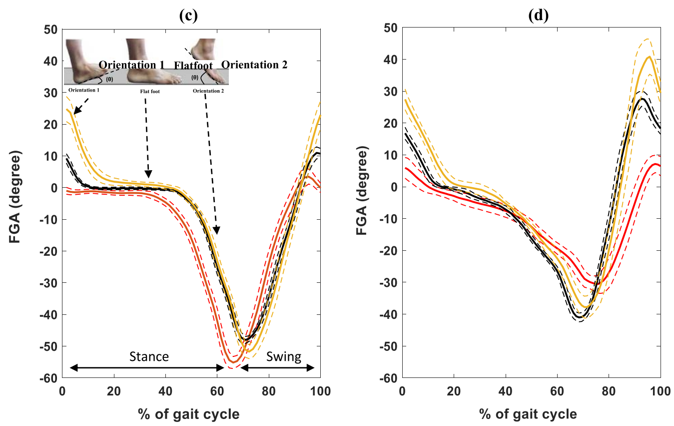

Fig. 9. Foot-to-ground angle (FGA) of a representative participant for three different walking conditions: baseline (——), FedAntCoP (——), FedPostCoP (——) where, dotted line represents the standard deviation and solid line represents the average value. (a)- A representative FGA from non-disabled participants as a percentage of the gait cycle. (b) -A representative FGA from amputee participant as a percentage of the gait cycle.

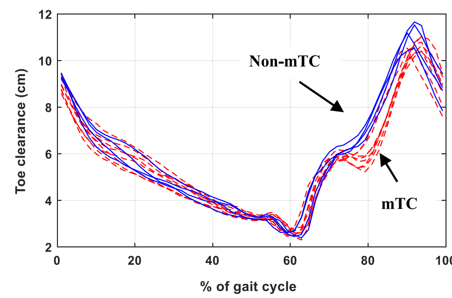

Fig. 10. A representative toe clearance mTC (red color) and non-mTC (blue color) stride as the percentage of the gait cycle.

differs significantly for both participants during the RetAntCoP, while during the RetPostCoP, it differs significantly ($p<0.05$) for non-disabled and did not differ significantly ($p>0.05$) for the amputee participants.

IV. Discussion

The objective of the current study was to investigate the effect of the visual feedback to shift the CoP anterior/posterior at heel strike on the toe clearance parameters among the non-disabled and transfemoral amputee participants. The mTC, $maxTC_1$, and $maxTC_2$ increased consistently for both non-disabled and the amputee participants during the posterior CoP shift condition, confirming the central hypothesis of the proposed work. This increase may possibly explain the transfer of energy from the stance phase to the swing phase during push-off. In non-disabled, it is possible that the increased propulsion during push-off may have been contributed from the increased trailing limb angle as well as the increased ankle plantarflexion moment. But in the case of the amputee participants, since the ankle joint is rigid and non-movable; therefore, the contribution to increase the propulsion force can be seen from the increase in trailing limb angle alone. Regardless these findings, in future a further investigation about the modulation in the propulsion force during CoP shift feedback is important to understand its effect on the toe clearance during swing phase. The other hypothesis i.e., anterior CoP shift would decrease the value of mTC and $maxTC_1$, was partly confirmed due to the occasional unexpected increase in the value of mTC and $maxTC_1$. However, the $maxTC_2$ did not show any increase in its value compared to the baseline value. The unpredicted increase in the value of mTC and $maxTC_1$ could be attributed to the compensatory strategy adopted by the participants in order to actively increase the toe clearance during the swing phase [56], [57], which is evident by a large number of non-mTC strides present within a trial. Nevertheless, as the $maxTC_2$ occurs nearly at the end of the swing phase just before the heel strike, the compensatory effect may not have affected it. Fig. 10 shows the representative trials from the anterior CoP shift feedback condition showing non-mTC (blue color) and mTC trials (red color). During retention, in amputees, mTC did not differ significantly (Table I) in contrast to non-disabled participants where mTC differ significantly from the corresponding feedback condition implies a strong positive effect of training on amputees compared to non-disabled participants. The possible reason for good feedback training retention in amputees compared to non-disabled participants could be learning of movement of the only pelvic joint in amputees, whereas in non-disabled individuals, the movement of all three joints has to be learned. We believe that in the future, a training protocol of long duration would help in better learning and retention.

The foot-to-ground angle (FGA) measurement in our study possibly explains the reason behind the change in the toe clearance parameters with the shift in the CoP during feedback. In non-disabled participants, the FGA_{mTC} increased during the posterior CoP shift condition, which suggests an active plantarflexion at the ankle position and therefore, an increased mTC may have been contributed either by the increased knee flexion or the hip flexion as these angles has a good amount of sensitivity to the mTC value [41]. The increased toe clearance in the amputee during anterior CoP shift condition contributed mainly by the active hip flexion and the passive knee joint flexion during the swing phase as the ankle contribution is zero because of the non-movable ankle joint. In the future, a detailed kinematic analysis would confirm this reasoning and reveal the underlying mechanism responsible for the increased toe clearance in the amputee population. The improvement in the toe clearance parameters with feedback for the amputee is less compared to the non-disabled participants, however, improved significantly from the baseline. This can be attributed to the more effective training during feedback in non-disabled participants compared to amputee due to involvement of active learning using biological motor pathways and controlled lower limb joint movement. Other factor which could explain less improvement of the toe clearance in amputees can be related to the different degree of ankle plantarflexion on the contralateral side in response to the feedback-imposed changes in the prosthetic limb, which may be responsible for altering the prosthetic toe height. In future, vaulting should be quantified using CoP and ankle kinetic/kinematic measurement to observe the effect of CoP shift feedback on alteration in vaulting mechanism. In contrast, during retention, the amputee showed better lasting effect of feedback training compared to the non-disabled participants. The fact that lower posterior displacement of the CoP in amputees (~4cm) (as shown in fig. 6(d)) compared to non-disabled participants (~3.5cm) (as shown in fig. 6(b)) could also be responsible for less improvement of toe clearance in amputee compared to non-disabled participants. The lower CoP shift posteriorly has been reported to reduce the propulsive force [57] and subsequently insufficient initial swing phase momentum [23]. The other possible reason for the limited posterior shift in the amputee could be an unhabitual walking during feedback which leads the amputee to instability during walking. This was observed during the experiment as amputees were taking support of the handrail of the treadmill during feedback walking. The support from the handrail of the treadmill might have also resulted in the decreased force being applied to the foot during the heel strike. We believe that increasing the training time of the amputee participants to some days or weeks would improve the stability and can improve the posterior shift in the CoP. In the future, a complement study with detailed lower limb kinematics and the electromyography analysis (i.e., how knee, ankle, and hip kinematic changes in response to the different feedback strategy) would enhance the potential understanding for explaining the improvement of the toe clearance. The average improvement in mTC for transfemoral amputees is 1.02cm which is nearly 40% improvement compared to the improvement achieved through motorized and actively dorsiflexing prosthetic ankle system, which has been shown to reduce the potential fall during one-year period [58]. Also, the improvement in mTC is comparable or higher to other previous studies involving clinical populations such as transtibial amputees with hydraulic ankle joint (~0.3cm) [4] and older adults (~1.3cm) [59]. Thus, the present approach can potentially lead to a fall-prevention mechanism in passive transfemoral prostheses. Moreover, enhanced prosthetic toe clearance may reduce intensity of the compensatory strategies employed for anticipated reduced toe clearance such as vaulting, circumduction, hip-hiking and thus may prevent undesirable gait deviations and may reduce long-term effects of these strategies such as back pain, excessive joint loading and osteoarthritis. The posterior CoP shift feedback may also reduce excessive strain on the intact leg for the requirement of forward propulsion of CoM during the late stance phase. On the negative side, the posterior CoP shift strategy in the prosthetic leg might induce enhanced socket limb interaction pressure due to possible increase in the hip extension moment during early stance and therefore, prosthetic socket with inner lining of soft material can be helpful to prevent stump skin damage in future. User's motivation during gait training is an important predictive factor for any successful rehabilitation program. Recent advancements in the development of wearable feedback systems that incorporates vibrotactile, electro tactile, or auditory sensory clue mapped to the specific spatial and temporal gait parameters for amputee's gait training facilitates them with enjoyable and non-obtrusive long-term training environment [60], [61]. In the future, the visual feedback system may be carefully replaced with the vibrotactile sensory clue through one-to-one mapping of the CoP spatial displacement to the different spatial location and/or varying intensity of the vibrotactile motors similar to our previous works [15], [62]. This strategy may envision the incorporation of posterior CoP shift feedback strategy in a wearable device inbuilt into the prostheses that can seamlessly provide real-time feedback training outside the laboratory environment. Interestingly, the posterior shift in CoP is correlated with the FGA_{mTC} in a way that FGA_{mTC} increased in orientation 1 (fig. 9(a)) during FedPostCoP for both non-disabled and amputee participates. Therefore, in the future, FGA feedback-based strategy instead of CoP based can be exploited to train the participants for simple and easy implementation of the wearable feedback system. In our study, during the feedback session, amputee walked at the speed (1.6±0.48 km/hr) which is less than the preferred walking speed of the amputees in general (around 70% of preferred walking speed [63]). This may be due to the compensatory strategy adopted by the participants to carefully place the foot on the treadmill while accurately shifting the CoP at heel strike through visual feedback screen placed in front of them. We believe that in future long-term training would increase the CoP displacement accuracy and thus amputee can walk with less cognitive demand at optimally higher speed while maintaining the similar mTC improvement. Also, the use of vibrotactile clue as a replacement to the visual clue in the future would reduce the cognitive burden and hence the amputee can maintain optimal speed with enhanced mTC. Despite some interesting interventions and outcomes, the present study suffers from some limitations as following- 1) the amputee population is limited to a smaller number which may impede the generalization of the results 2) the training time is short, which could be increased to days to a week to understand the effect of biofeedback in a better way. 3) Although treadmill simulates the floor walking environment, we believe that use of treadmill compromises the performances of the training such as to accustomed with the treadmill walking takes time, controlled speed of the treadmill may influence the natural walking pattern, sometimes lead to walking instability and perturbations, and increases the energy cost of walking [64]. In the future, training over floor walking would enhance the training performance.

V. Conclusion

The present CoP-based visual feedback approach can potentially be more effective in improving minimum toe clearance in amputees with long-term training. The visual-feedback training approach was conducive with user-friendly instrumentation. The entire experimental setup (insole for CoP measurement and instrumented shoe) may be converted in a wearable device with vibrotactile feedback. The effectiveness of the proposed training feedback scheme was noticed during the retention session. Using the foot-to-ground angle, a likely explanation of improved mTC was conceptualized. The present study is a proof of concept and therefore limited to few participants. In the future, we intend to include more clinical participants with transfemoral and transtibial amputation. The visual feedback training to modulate CoP during heel strike may be studied in future for elderly and other clinical population including Parkinson's and stroke to improve gait parameters.

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