

Effect of shod walking on plantar pressure with varying uphill gradients



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ABSTRACT

Background: Uphill walking is biomechanically stressful. Changes in plantar pressure, is one of the important predictors of this stress and increased risk of foot injuries. It has been reported that civilians as well as different occupational workers have to walk over uphill gradient with footwear which may cause changes in plantar pressure. Till date published data on plantar pressure is not available of Indian population during shod walking with uphill gradients. **Aims and Objective:** The present study was aimed to generation of data base on plantar pressure and find out the effect of shod walking (wearing occupational boot) on plantar pressure at different uphill gradients. **Materials and Methods:** Twenty healthy male participated in this study. Plantar pressure was recorded using the pressure measurement system during walking at 4 km/hr speed on treadmill at level and different uphill gradients. **Results:** It was observed that the PP at all the five regions of both right and left foot (Forefoot, Mid-foot, Medial, Lateral, Heel and Overall) increased gradually along with the increase in gradients. There was significant increase of 8.94%, 9.93%, 18.22%, 16.06%, 10.27%, 12.92% respectively at left forefoot, mid-foot, heel, medial, lateral and overall regions at 10% gradient compared to level walking. Similarly, in right foot the increase was observed 8.20%, 10.82%, 14.28%, 13.75%, 8.27%, 10.88% in respective foot regions compared to level walking. **Conclusion:** Observations of the present study stated that with increasing gradient plantar pressure at various foot regions increased in both feet in comparison to level walking, maximum plantar pressure observed in heel region in both feet in comparison to other studied regions. This data will be considered as normal planter pressure value of adults at level and uphill gradients shod walking and may be utilized for prognosis of foot disorders and efficacy of treatment modalities of population comparable with studied individuals (for similar age, height and weight).

Key words: Plantar pressure; Foot regions; Uphill walking; Foot injury risk

INTRODUCTION

During walking interactive forces are transferred between the human body and ground. Measurement of these ground contact forces in an unit of foot area can be used to assess the external load to which human body is subjected to expose in different situations. This form of mechanical pressure is termed as plantar pressure (PP). According to Mueller, pressure is a form of mechanical stress, which is equal to the magnitude of the perpendicular force to a specific surface area. Information derived from such pressure

measures is important for diagnosing lower limb problems, footwear design, sport biomechanics, injury prevention and other applications.¹ Various anthropometric and kinematic factors have been identified which affect the PP. Age related differences have been described between children and adults.² There are a lot of differences between adult and elderly population. Ageing is associated with significant changes in foot characteristics which contribute to altered plantar loading patterns during gait. Older people exhibit flatter feet, reduced range of motion, tactile sensation and strength, and a higher prevalence of foot deformities.³

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Gender also affects the pattern of plantar loading as Queen et al. found that PP value is significantly higher under the forefoot region of the male subjects during gait.⁴ Foot shape is another important factor which may cause the plantar loading variation. Different foot structures like cavus or planus foot deliberately reveals different pressure distribution patterns. Higher amount of pressure has been found in mid-foot region of planus foot and central forefoot region in cavus foot.⁵ Gait velocity can also change the plantar loading pattern. There was a linear increase in heel and medial forefoot with increasing speed whereas in mid-foot and lateral region it was decreased with speed.⁶

There have been ample advancements in PP measurement over the recent times in understanding the pressure generated by the feet during human locomotion, both qualitatively and quantitatively. Information from these measurements have provided essential support in the assessment of various foot pathologies, including rheumatoid arthritis,⁷ Parkinson's disease,⁸ and diabetes,⁹ and peripheral neuropathy.¹⁰ Accordingly clinicians used to suggest the appropriate insole/footwear to alleviate the pressure problems. Measurement of PP has immense importance in the domain of sports biomechanics for predicting the risk of slip and fall; bone, ligament, tissue injury/fracture; efficacy of the footwear etc.¹ One of the earliest applications of PP was the evaluation of footwear. Lavery et al.¹¹ in 1997 determined the effectiveness of therapeutic and athletic shoes with and without visco-elastic insoles using the mean peak plantar pressure as the evaluation parameter. Mueller¹² applied plantar pressure to the design of footwear for people without impairments (i.e., the civilian population). Furthermore, Praet and Louwerens¹³ and Queen et al.⁴ found that the most effective method for reducing the pressure beneath a neuropathic forefoot is using rocker bottom shoes and claimed the rocker would decrease pressure under the first and fifth ray (metatarsal head). Another research area of plantar pressure measurement is to design footwear to fulfill the occupational requirements. For example, shoes may need protective or traction properties in order to allow the individual to safely and effectively carry out a required task. One such occupation is mining, which requires workers to stand for long periods of time on sometimes uneven, wet or unstable surfaces. In a group of miners it was observed that increased incidents of foot pain was due to the mismatch of width of the existing shoes.¹⁴ Contact areas of foot, maximum force, maximum pressure and average pressure have influencing effect on PP. It was found in hikers that comparatively light weight shoes are more beneficial in terms of increased feelings of comfort and fit due to increase in the contact area and decrease in peak pressure. Thus, fatigue at foot and pelvic limbs were delayed.¹⁵ As discrete occupational group, soldiers are also highly mobile in their daily work schedule, which involves variety of maneuvers like normal walking, marching,

running, jumping, jogging etc. These maneuvers can be the part of their regular training as well as a real time combat scenario. Moreover, these activities have to be carried out over a range of terrain conditions namely mountainous/hilly, jungle, desert etc. Among these, mountain terrain is mostly characterized with hard rocks and uphill gradients. Vigorous movements in these terrains engross repetitive and frequent uphill walking which can be especially challenging for the individual. During their course of movements there is a high intensity kinetic interaction between foot and contact surfaces. The degree of changes depends on the physical property of the surface. These vigorous movements of soldiers over multiple terrains with elevations may lead to changes in plantar pressure in different foot regions. It can immensely contribute to strains and sprains in the legs, and they may experience muscle knots in their various lower limb muscles. In addition, high pressures may be felt at the plantar surface from ill-fitting footwear which may lead to pain sensation to the wearer. The physiological and biomechanical stress of uphill walking has been evaluated in normal civilian population by recording the changes in oxygen consumption and muscular activities.^{16,17} Scanty of studies have reported the biomechanical stress by recording the changes in PP during inclined gait by assessing the civilian population only.¹⁸⁻²¹ Considering the global scenario, only a very few studies have been reported regarding the biomechanical stress under various occupational condition. It was observed that 53000 valuable training days were lost and \$ 16 million compensation amount was levied per year due to musculoskeletal complaints among the US navy personnel. To find out the underlying root cause of this problem, kinetic recordings were conducted during walking, marching and running and it was suggested to bring about improvements in the forefoot cushioning of combat footwear.²²⁻²⁵ Trone et al. evaluated the biomechanical properties of available boots and provided recommendations for optimum biomechanical properties.²⁴ In German army, the cushioning properties of army footwear have been identified as insufficient and related to a higher risk for injuries.²⁶ Evaluating the effects of slope/gradient walk on the changes in plantar pressure at various foot regions, is relatively a growing field of research. A scanty of research attempts have been done till date. The present study was aimed to generation of data base on plantar pressure and find out the effect of shod walking (wearing occupational boot) on plantar pressure at different uphill gradients.

MATERIALS AND METHODS

Participants

Twenty (n=20) physically fit Indian healthy male without any previous history of musculoskeletal disorders, fractures, disorders of the locomotors or vestibular systems

etc, volunteered for the study. Their mean (\pm SD) age, height and weight were 40.05 (\pm 6.41) years, 168.95(\pm 6.80) cm and 75.55 (\pm 8.30) kg respectively. Before the commencement of the experiments the participants were acquainted with the experimental design and their informed written consent were taken.

Ethical clearance

The study protocol was approved by the Institutional Ethics Committee on the use of the human as the experimental subjects and the experiment conforms to the principles outlined by the declaration of Helsinki protocol, 1985.

Experimental protocol

A week prior to undertaking the experiments, the subjects routinely wore the boots provided for habituation during their duty hours. At first participants were habituated to walk on the motorized treadmill at various gradients in the laboratory. This attempt reduced the chances of slip and fall during the experiments. Participants fitted with foot scan insole (M/s Medilogic 5.8, Germany) as per their foot dimension (just beneath the skin of their own plantar surface of both feet) and the cables from each insole were connected to the data logger modem which was tightly fitted at the waist region using a waist belt. Each participant underwent on treadmill for six minutes at each gradient (0%, level), (5% and 10% uphill) at 4 km/hr walking speed. During experiment each participant wore regular combat boot (weight-1.5 kg). Plantar pressure was measured continuously for six minutes walking by using foot scan insole and whole six minutes' data was considered for processing and statistical analysis. All the experiments have been conducted in a controlled laboratory environment of 23- 25 °C, 36-45% relative humidity and at the same time of the day (1030 h and 1300 h).

Parameter

Plantar pressure (N/cm²* s) in five different foot regions i.e. Forefoot, Mid-foot, Lateral, Medial and Heel and overall plantar pressure of foot.

Statistical analysis

Descriptive statistics in the form of mean and standard error of mean (SEM) of the raw data of different parameters were calculated. One-way repeated measure ANOVA was conducted to observe the significant effect of experimental independent variables i.e. changes in gradient (0, 5, 10) % on experimental dependent variables, i.e. Plantar pressure at different foot regions (forefoot, mid-foot, heel, medial, lateral, overall) followed by overall significance a pair-wise Bonferroni post Hoc test was conducted to find out the significance of PP changes for comparison between one pair of gradient. A correlation was conducted in predicting strength of relation between

overall pressure and the pressure of specific region of foot separately across all gradients for individual foot. Application of partial correlation estimated an absolute correlation between overall pressure and a pressure of specific foot region while controlling the effects of other foot regions.

RESULTS

Changes in plantar pressure in both left and right foot were increased gradually during walking uphill gradients (5%, 10%) in comparison to level. Forefoot, heel, mid-foot, medial, lateral, overall plantar pressures were increased (Table 1) Results of one way repeated measures ANOVA revealed that gradients caused significant changes in PP in left heel [$F_{(2, 36)} = 18.28$; $P < 0.05$], Forefoot [$F_{(2, 36)} = 5.99$; $P < 0.05$], medial [$F_{(2, 36)} = 30.29$; $P < 0.05$], lateral [$F_{(2, 36)} = 9.02$; $P < 0.05$], and overall [$F_{(1.26, 22.67)} = 29.46$; $P < 0.05$]; and right heel [$F_{(1.29, 23.24)} = 7.15$; $P < 0.05$], forefoot [$F_{(1.63, 29.46)} = 4.48$; $P < 0.05$], medial [$F_{(1.98, 35.62)} = 18.47$; $P < 0.05$], overall [$F_{(2, 36)} = 31.17$; $P < 0.05$] (Table 2). From pair wise comparison it was observed that in heel region plantar pressure was increased by 18.22% in left foot which was statistically significant ($P = 0.000$) when compared to level. Similarly, right heel pressure was more affected by 10% gradient than left heel. In left medial region of foot there was an increase of 15.18% and 16.06% respectively in 5% and 10% and likewise in right medial region there was an increase of 11.84% and 13.75% which were found statistically significant when compared with level walking ($P < 0.05$). On the contrary in forefoot and mid foot region of both feet, there was no significant change observed in PP. However, in left mid-foot region the percentage of increase in PP were observed 10.42% and 9.93% respectively at 5% and 10% gradient. The results also showed that overall plantar pressure was significantly increased by the effect of slope ($p < .001$) in both feet. Pair-wise comparison revealed significant maximum increase of 12.92% in overall PP while walking 0 % to 10% gradient in left foot. Whereas in right foot significant increase of PP by 10.88% was only found in 10% gradient (Table 2). It can also be observed from the results that heel region in both feet were mostly affected by gradient comparing with other regions.

Correlations among the overall plantar pressure and pressures at different foot regions of both feet across all uphill gradients are presented in Table 3. The results of partial correlations revealed the entire strength categories viz. low, moderate and high ranging from 0.072 to 1.00. In left foot, it was found that overall pressure significantly correlated with medial pressure at all gradients as well as level walking ($r = 0.967$ at 0%, $r = 0.967$ at 5% and $r = 0.975$

Table 1: Mean ± SEM, Percentage changes of plantar pressure (N/cm²*s) of different foot regions in both feet at different gradients (0%, 5% & 10%)

Foot Regions	Gradient			% changes		
	0%	5%	10%	0 Vs. 5	0 Vs. 10	5 Vs. 10
Left Forefoot	4.72±0.05	5.23 ±0.05	5.18 ±0.05	9.73↑	8.94↑	0.87↓
Right forefoot	5.13 ±0.05	5.55 ±0.05	5.59±0.05	7.57↑	8.20↑	0.69↑
Left mid-foot	2.54 ±0.05	2.83 ±0.05	2.82 ±0.05	10.42↑	9.93↑	0.55↓
Right mid-foot	2.61 ±0.05	2.88 ±0.05	2.93±0.05	9.30↑	10.82↑	1.67↑
Left lateral	4.91 ±0.05	5.27 ±0.05	5.47 ±0.06	6.95↑	10.27↑	3.56↑
Right lateral	5.04 ±0.05	5.29 ±0.05	5.50 ±0.06	4.65↑	8.27↑	3.80↑
Left medial	4.03 ±0.04	4.75 ±0.04	4.80 ±0.04	15.18↑	16.06↑	1.05↑
Right medial	4.35 ±0.04	4.93±0.04	5.04 ±0.04	11.84↑	13.75↑	2.16↑
Left Heel	5.80 ±0.06	6.59±0.06	7.09 ±0.08	11.94↑	18.22↑	7.13↑
Right Heel	5.90 ±0.05	6.45 ±0.06	6.89 ±0.07	8.45↑	14.28↑	6.36↑
Left overall	4.46 ±0.04	5.00 ±0.04	5.12 ±0.05	10.85↑	12.92↑	2.32↑
Right overall	4.59 ±0.05	5.10 ±0.05	5.15 ±0.05	10.03↑	10.88↑	0.94↑

↑ indicates % increase in PP; ↓ indicates % decrease in PP

Table 2: Effect of uphill gradients on the plantar pressure in both feet under three different experimental conditions

		F value	P value	df	Pair-wise comparison		
					0 vs 5%	0 vs 10%	5 vs 10%
LEFT FOOT	Overall	29.46	0.000*	(1.26, 22.67)	0.000*	0.000*	0.002*
	Heel	18.28	0.000*	(2, 36)	0.000*	0.000*	0.525
	Forefoot	5.99	0.006*	(2, 36)	0.08	0.008*	1.00
	Mid-foot	2.69	0.10	(1.39, 24.97)	0.429	0.007*	1.00
	Medial	30.29	0.000*	(2, 36)	0.000*	0.000*	1.00
RIGHT FOOT	Lateral	9.02	0.001*	(2, 36)	0.01*	0.000*	1.00
	Overall	31.17	0.000*	(2, 36)	0.24	0.000*	0.000*
	Heel	7.15	0.009*	(1.29, 23.24)	0.407	0.000*	0.20
	Forefoot	4.48	0.03*	(1.63, 29.46)	0.407	0.002*	0.92
	Mid-foot	1.30	0.28	(1.32, 23.82)	0.8	0.05*	1.000
	Medial	18.47	0.000*	(1.98, 35.62)	0.05*	0.000*	0.009*
	Lateral	3.2	0.08	(1.28, 23.12)	0.93	0.002*	0.73

* indicated the values are significant at P<0.05

Table 3: Partial correlation between overall pressure and pressure at other regions of foot across all gradients in both feet

Correlation Parameters	Correlation values	Left foot			Right foot		
		0%	5%	10%	0%	5%	10%
OA X FF	r value	0.236	0.305	0.000	-0.062	-0.830	0.172
(controlling for H, MF, MD, LTR)	Significance	0.379	0.269	1.000	0.818	0.000*	0.467
OA X H	r value	0.182	0.344	0.000	-0.182	-0.126	1.000
(controlling for FF, MF, MD, LTR)	Significance	0.501	0.209	1.000	0.501	0.654	0.000*
OA X MF	r value	0.276	0.429	-0.916	-0.117	-0.193	0.072
(controlling for FF, H, MD, LTR)	Significance	0.301	0.111	0.000*	0.667	0.490	0.762
OA X MD	r value	0.967	0.968	0.975	0.315	0.257	0.431
(controlling for FF, H, MF, LTR)	Significance	0.000*	0.000*	0.000*	0.235	0.355	0.058*
OA X LTR	r value	0.965	0.967	0.219	0.231	0.274	0.74
(controlling for FF, H, MF, MD)	Significance	0.000*	0.000*	0.354	0.389	0.322	0.000*

OA= overall plantar pressure, H=Heel pressure, MF= Mid-foot plantar pressure, MD= Medial plantar pressure, LTR= Lateral plantar pressure, (*) = P<0.05

at 10% gradient). Whereas, a high and significant correlation was observed between overall pressure and lateral pressure in level ($r= 0.965$) and 5% gradients ($r= 0.967$). In 10% gradient overall pressure was significantly correlated with mid-foot ($r= -0.916$). In right foot, overall pressure was

strongly correlated with forefoot pressure at 5% gradient only ($r= -0.83$). In 10% gradient, heel and lateral pressure were also strongly correlated with overall pressure ($r= 1.000$, $r= 0.74$). Medial plantar pressure was also correlated with overall pressure but that is weak ($r= 0.431$).

DISCUSSION

The present study was aimed to generation of data base on plantar pressure and find out the effect of shod walking (wearing occupational boot) on plantar pressure at different uphill gradients on treadmill. Observations of the present study are as follows- with the increase in gradient plantar pressure at various foot regions increased gradually in both feet in comparison to level walking, and maximum plantar pressure observed in heel region in both feet in comparison to other studied regions. It was observed that the PP increased in all regions of the foot with the increasing gradients in both feet. These observations are contrasted by the findings of the previous studies.^{18,19} Ho et al.¹⁸ conducted experiments with the variation of gradients (0, 5, 10, 15 %) and speed (5.4, 7.5, 9 km/h) to observe the changes in PP where it was found that heel peak pressure reduced by 27% from 0% to 15% inclination. On the contrary, the PP increased by 33% at this region with the increase of speed from 5.4km/h to 9 km/h and finally interpreted that speed is mostly contributing in the process of changes in PP compared to changes in gradient. Almost similar observation was found by Grampp et al.¹⁹ following a protocol with manipulation of only gradient factor i.e. uphill and downhill (-15%, -8.5%, Level, 8.5%, 15%) and concluded that with the increasing gradient the plantar loading increased in the forefoot region and decreased in heel region. Thus, these discrepancies in the observations between the present study and the previous studies (as discussed formerly) may be explained by the adaptation to the individual's gait pattern to increasing gradient at a constant speed (a moderate walking speed) for the present study and increasing speed (either running or jogging) at a constant gradient for the study by Ho et al. Hence, it can be postulated in majority of the cases PP may be influenced by the condition of speed of mobility i.e. walking, jogging and running which is irrespective of increase in gradients. They reported a decrease in the duration of the stance phase with increased walking speed. As speed increased, step length in both young adults and older adults, and stride length in older adults, also increased, corroborating the findings of a previous study.²⁷ The effects of gait speed on the minimum and maximum values of joint angles have also been reported, including increases in hip flexion, hip extension, knee flexion, and ankle plantar flexion angles with higher speeds.²⁸ Although for present study, it was observed that the pressure increased proportionately with the increasing gradient while maintaining a constant walking speed. Besides the influence of variations in speed and gradient there are other major methodological independent factors like variation in duration of the treadmill walking (present study for 6 minutes walking, Ho et al. for 30 seconds,¹⁸ Grampp et al. for 2 minutes;¹⁹ and analysis of recorded

data either for entire experiment duration or fraction of the data from entire duration (present study presented data of entire experiment duration, Ho et al. presented 30 seconds data,¹⁸ Grampp et al. presented last 20 seconds data,¹⁹ data presented from single foot or both feet (for present study data presented separately for both feet, Ho et al. not mentioned,¹⁸ Grampp et al. presented only right foot data.¹⁹ Type and morphology of footwear also played vital role in distribution of PP at various regions of the foot. Dong et al. found that increasing heel height and inclination resulted in increasing PP in mid-foot and decrease in heel.²¹ Park et al. demonstrated that using footwear made of PLA (poly lactic acid resins) resulted in greater contact area and reduced peak pressure and maximum force in comparison with a regular control boot during treadmill walking.²⁹ Moreover, Keijsers et al. demonstrated that individual characteristics like age, weight, height, foot width, foot length, contact time and gender are also having influencing effect on PP.³⁰

The second important observation of the present study was that the most prone affected region to injury identified as heel compared to other foot regions (Figure- 1-4). This finding is partly corroborated with the findings of Park et al. where it was found that peak pressure, maximum

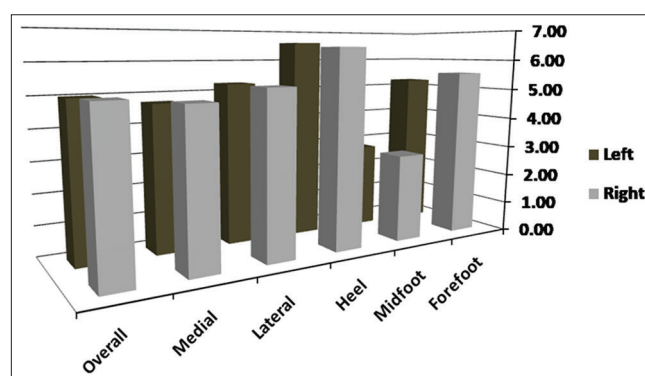


Figure 1: Graphical representation of plantar pressure of different foot regions in the right and left foot at 0 % gradient with walking speed of 4km/h walking speed

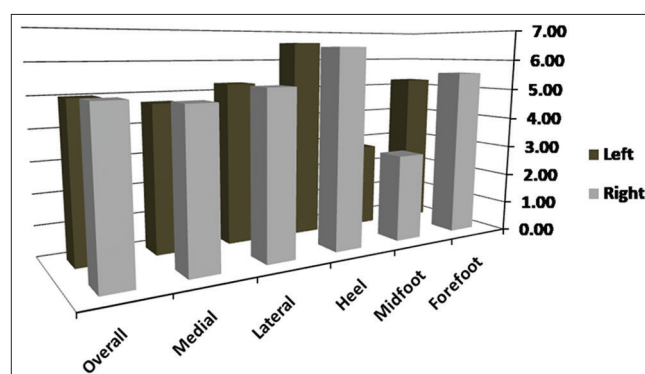


Figure 2: Graphical representation of plantar pressure of different foot regions in the right and left feet at 5% gradient with walking speed of 4km/h walking speed

mean pressure and maximum force were lesser in mid-foot compared to forefoot and heel irrespective of shoe type.²⁹ It was also found that PP at left heel region increased compared to right foot whereas PP in other regions of right foot was found higher than left. Rai et al. observed that 17% of the experimental population executed equal pressure on both feet, 7% showed greater pressure on left foot and 76% found higher load on the right foot.³¹ Hence it can be stated that impact of gradient on right foot was more than left foot and it may be due to the effect of dominance of leg.

Another important factor was the way of presentation of plantar pressure. Majority of above mentioned studies¹⁸⁻²¹ analyzed only mean and peak pressure values of each trial whereas present study considered whole time frame of the trial and analyzed pressure time integral. It is the value of plantar pressure which seems to be more accurate as considering the relationship between plantar pressure and foot pain. A pressure time integral is the representative of magnitude of pressure as well as the rate at which pressure is loaded.³² The calculation is done as the sum of peak

pressure in each frame of foot contact multiplied by the duration of foot contact. Higher pressure–time integrals recorded in our study were predominantly resulted from the increased duration of foot contact and peak pressure as demonstrated by Burns et al.³³ Uphill walking induced fatigue in the legs resulted in higher pressure time integral which in turn alters normal gait dynamics of both feet.^{34,35}

Different strength of correlation between overall PP and pressure at specific region of both feet were observed with the increase in gradient. As overall PP is a resultant measure of pressure at forefoot, mid-foot, medial, lateral, and heel, it was important to establish relation between overall PP and pressure at specific region with an approach of partial correlation. Left medial and lateral PP was found with a strong correlation with Overall PP across all gradients. In right foot, forefoot PP was strongly correlated with overall PP at 5% gradient. Therefore, it can be postulated that increase in forefoot PP is an indicator of increased overall pressure. Similarly, at 10% gradient overall PP was strongly correlated with heel, medial and lateral PP for both feet. Right heel PP at 10% gradient showed highest correlation ($r=1$) with overall PP which depicted that right heel region was more susceptible than any other region of the foot contributing mostly for increase in overall PP with increased risk of injury at higher gradient.

CONCLUSION

This data will be considered as normal planter pressure value of adults at level and uphill gradients shod walking and may be utilized for prognosis of foot disorders and efficacy of treatment modalities of population comparable with studied individuals (for similar age, height and weight). Observations of the present study may be beneficial in

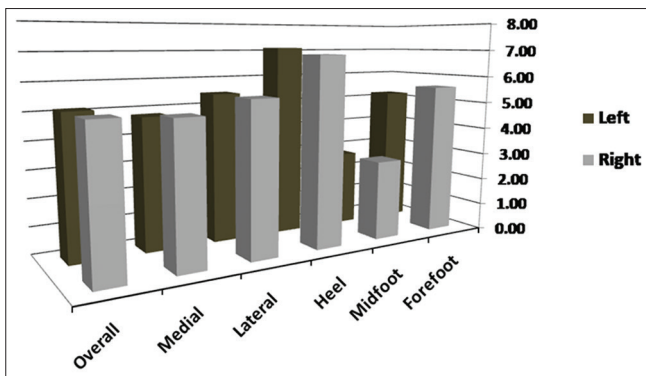


Figure 3: Graphical representation of plantar pressure of different foot regions in the right and left feet at 10% gradient with walking speed of 4km/h walking speed

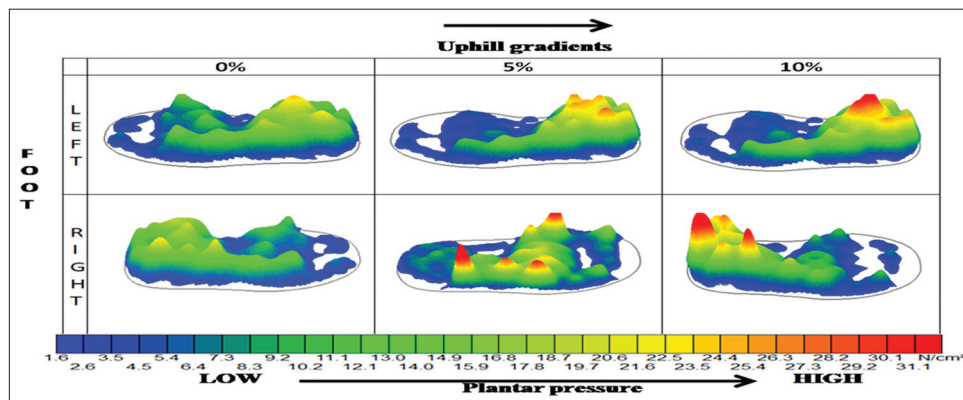


Figure 4: Pedobarographical presentation of plantar pressure of both feet, In left foot higher plantar pressure observed at heel region (visible as red area) in comparison with the other foot regions with increasing gradient. Same pattern of pressure distribution was also observed in right foot with increasing gradient. Pressure distribution in all regions with increasing gradient is higher in right foot than left foot. Exception was observed in 5% gradient where heel pressure is lesser in right foot in comparison with left foot

conveying a practical knowledge towards the designing of various occupational/functional footwear with improved design features and advanced cushioning at foot bed for reducing the risk of injuries by minimizing planter pressure under adverse occupational environment.

Limitations of study

Present study was limited to the application of only two uphill gradients (5 and 10%) at a constant speed (4.0 km/hr), and male subjects. Therefore, future studies may be directed to inclusion of other uphill as well as downhill gradients, different walking speed, sex and age variation, effect of dominance of leg, different footwear.

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ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This research was completed under the ethical approval of the Institutional ethics committee of DIPAS, DRDO.

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Author's contributions:

SS- Data collection, analyzed, reviewed the literature, interpreted results, manuscript preparation; **DB-** Study design, statistical analyzed, interpreted results, revision of manuscript; **SC-** Data collection, analyzed, reviewed the literature; **BK-** Critical revision of the manuscript, interpretation; **MP-** Concept generated, finalized study design, overall coordination and supervision of the study.

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