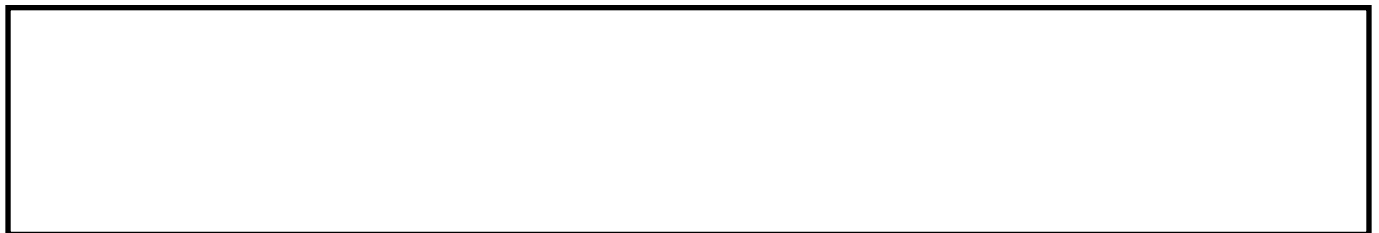


HAZARI, A., MAIYA, A., AGOURIS, I., MONTEIRO, A. and SHIVASHANKARA. 2019. Prediction of peak plantar pressure for diabetic foot: the regressional model. The Foot [online], 40, pages 87-91. Available from: <https://doi.org/10.1016/j.foot.2019.06.001>

Prediction of peak plantar pressure for diabetic foot: the regressional model.

HAZARI, A., MAIYA, A., AGOURIS, I., MONTEIRO, A., SHIVASHANKARA.

2019



RESEARCH PAPER HIGHLIGHTS

KNOWN FACTS- Diabetes Mellitus is a potential epidemic in Asia and India being the diabetic capital. Diabetes causes various foot complications with underlying peripheral neuropathy. The most important etiological factor for a diabetic foot is high/altered plantar pressure.

Novelty and Highlights:

1. The study determined the peak plantar pressure difference between type 2 diabetes mellitus with and without neuropathy
2. The study focused on the most important clinical parameters that could be associated with peak plantar pressure in type 2 diabetes mellitus participants.
3. The clinical variables like severity of neuropathy, varicosity, plantar cushioning, dynamic knee joint angle, and angular ankle joint velocity were important predictors for peak plantar pressure.

Title: A Clinical Tool For Diabetic Foot Prediction: The Regression Model

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Prediction of Peak Plantar Pressure for Diabetic Foot: The Regression Model

Abstract:

Background: The increase in peak plantar pressure could be the most important etiological factor for pathogenesis of a Diabetic Foot. Thus the fate of a diabetic foot syndrome which is a clinical triad of neurological, vascular and musculoskeletal changes could be biomechanically predictive and preventive using clinical parameters. In the presence of peripheral neuropathy, certain clinical parameters could be severely altered resulting into increased peak plantar pressure. Therefore the aim of the study was to identify the most important clinical parameters for the prediction of peak plantar pressure between neuropathy and non-neuropathy type 2 diabetes mellitus participants. Methodology: A total of 380 participants were recruited under the study and divided into two groups (190 each group). The cross-sectional study was conducted at Kasturba Hosipal, Manipal,India. Multiple regression analysis was performed to find the hyperplane of best fit. Stepwise regression was performed with α (entry=.15 and α removal=.2) to select the best subset of predictors. Results: Adjusted R² of the final model which included the predictors showed 90.8% variability for the dependent variable. Conclusion: The findings from the regression analysis and suggested model was found be strongly significant in predicting the peak plantar pressure between neuropathy and non-neuropathy type 2 diabetes mellitus participants. Since higher values of peak plantar pressure is strongly associated with risk for future diabetic foot complications, it could be suggested that these clinical parameters could be very useful to assess and should be used in routine clinical practice very effectively.

Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),

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60 **INTRODUCTION:** Foot complications are the most ignored part of diabetes
61 management. The increase in peak plantar pressure could be the most important
62 etiological factor for pathogenesis of a Diabetic Foot [2]. Diabetic Foot Syndrome
63 (DFS) as defined by the World Health Organization is an “ulceration of the foot
64 (distally from the ankle and including the ankle) associated with neuropathy and
65 different grades of ischemia and infection” [3]. Thus the fate and pathophysiology
66 of a diabetic foot syndrome include a clinical triad of neurological, vascular and
67 musculoskeletal changes which could be biomechanically predictive and
68 preventive using clinical parameters. In the presence of peripheral neuropathy,
69 certain clinical parameters could be severely altered resulting into increased peak
70 plantar pressure [1]. For e.g. the sensory deficit leads to common foot
71 complications like altered sensations (tingling, burning, pricking, hypoesthesia,
72 allodynia). The sensory deficit could be clinically manifested with the loss of
73 protective sensation initially (touch and temperature), and progression to damage
74 of large diameter sensory fibers (vibration loss) [4]. The motor neuropathy presents
75 as weakness and atrophy of intrinsic and extrinsic foot muscles at ankle, and leads
76 to common foot deformities like claw toes, hammer toes, equinus, Charcot foot,
77 changes in foot arch, tightness of plantar aponeurosis, etc. The primary changes in
78 the musculoskeletal structures could also be associated with consequent secondary
79 changes in joint structure and function like the decreased range of motion [5]. The
80 vascular changes are often seen as reduced blood supply to peripheral
81 microvasculature of foot. Vascular insufficiency may be clinically manifested by
82 the altered ankle brachial index (ABI), blackish discoloration of the foot, altered
83 temperature of the foot. Autonomic neuropathy and dermatological changes are the
84 most common manifestation that accounts for 47.5-91.2 % of people with type 2
85 diabetes mellitus [6]. Decreased blood circulation can lead to changes in the skin
86 collagen altering its texture, appearance, and ability to heal. As a result, the skin’s
87 Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
88 Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),
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116 59 endothelial cells get damaged, and this may even reduce its ability to sweat which
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118 60 leads to dry skin, fissure and callus formation as well as a decrease in the ability to
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120 61 sense temperature and pressure [7]. Studies have reported that the increase in peak
121
122 62 plantar pressure and repetitive micro trauma due to higher ground reaction force
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124 63 (GRF) could be the most important etiological factor for pathogenesis of a DFS
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126 64 [8]. Similar findings were supported by another study which concluded 57% higher
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128 65 risk for ulceration at high pressure points. The individual areas of foot like hallux,
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130 66 metatarsal heads, midfoot and heel were positively associated with the peak plantar
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132 67 pressure and incidence of foot ulcers [9]. While studying the presentation and
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134 68 causative factors, it is now understood that DFS could be biomechanically
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136 69 determinative predominately by increased plantar pressure/ ground reaction force.
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138 70 Thus with a detailed clinical evaluation, and identification of clinical parameters
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140 71 which could be closely associated with high plantar pressure, the risk of future
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142 72 diabetic foot complications could be predicted and prevented. Therefore the aim of
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144 73 the study was to identify the most important clinical parameters of diabetic foot
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146 74 which could be the predictors of the peak plantar pressure in diabetic foot. The
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148 75 objectives of the study were as follows:

148 76 1. To find a line of hyper plane between the neurological, vascular, musculoskeletal
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150 77 and biomechanical findings with maximum/peak plantar pressure among
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152 78 participants with type 2 diabetes mellitus.

154 79 2. To provide regression equation and prediction model for peak plantar pressure
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156 80 distribution between neuropathy and non-neuropathy type 2 diabetes mellitus
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158 81 participants.

160 82 **METHODOLOGY:**

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166 Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
167 Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),
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172 83 **Study Design and Settings:** The observational cross-sectional study was
173 84 conducted at Diabetic Foot Clinic, Kasturba Hospital, Manipal, Karnataka India.
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175 85 The study is a part of PhD.
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178 86 **Study Population:** All diagnosed type 2 diabetes mellitus participants were
179 87 recruited under the purposive sampling method. A total of 380 participants (the
180 88 sample size was taken as a part of PhD study using the formula for comparison of
181 89 mean for outcome like peak plantar pressure) were recruited under the study. The
182 90 participants were divided into two equal groups (n=190 each) in order to
183 91 determine the change in plantar pressure distribution and its association with
184 92 clinical parameters between participants with type 2 DM with neuropathy and type
185 93 2 DM without neuropathy . Neuropathy subjects have been graded and compared
186 94 with non-neuropathy group as the reference in the equation
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195 95 **Study Procedure:** The ethical clearance for was obtained from Institutional Ethics
196 96 Committee. An informed consent was obtained from all participants following
197 97 which a detailed diabetic foot evaluation was taken including neurological,
198 98 vascular, musculoskeletal and biomechanical findings. It is well known that plantar
199 99 pressure is severely affected by presence of peripheral neuropathy. Therefore
200 100 screening for the presence of diabetes peripheral neuropathy is important. The
201 101 presence of neuropathy was confirmed with findings from Monofilament and
202 102 Vibration pressure threshold (VPT) values. The VPT values were also used to
203 103 further stratify the grades of neuropathy. A value of 1 to 14 volts was reported as
204 104 the absence of neuropathy, 14 to 20 volts as a risk for neuropathy, and values
205 105 above 20 volts were considered as neuropathy among Indian population based on
206 106 previous literature [10].The protective sensation testing was performed using the
207 107 standard procedure for 5.07/10g Semmes Weinstein Monofilament Test and
208 108 vibration sense testing using biothesiometer (Vibration Pressure threshold
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Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),

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227 109 Device/VPT). Semmes Weinstein 10 g Monofilament Testing is a widely used
228 110 neuropathy screening tool in diabetes mellitus. A systematic review was done on
229 111 the use of Semmes Weinstein Monofilament as a diabetic neuropathy screening
230 112 tool used in various studies. The study concluded that it had a sensitivity ranging
231 113 from 57% to 93%, specificity ranging from 75% to 100% and a positive predictive
232 114 value ranging from 84% to 100% whereas negative predictive value is ranging
233 115 from 36% to 94% [11]. Similar to 10 g Monofilament, VPT testing is a valid,
234 116 reliable and cost-effective clinic tool to diagnose neuropathy compared to a gold
235 117 standard like Nerve Conduction Velocity. A study was conducted by Kaur and
236 118 Singh (2016) to test VPT as a measure of distal symmetrical polyneuropathy
237 119 (DSPN) in type 2 diabetes mellitus [12]. The study concluded that VPT was a
238 120 reliable measure for DSPN with good sensitivity (74.07%) and specificity to
239 121 diagnose clinical neuropathy. Following the confirmation of DPN, other clinical
240 122 variables were obtained which consisted of more than 150 direct variables and 348
241 123 sub-variables into the assessment. The variables includes in the study were
242 124 selected and categorized based on the standard diabetic foot evaluation and their
243 125 association with maximum plantar pressure. In the present study we have listed the
244 126 variables that could alter the plantar pressure directly or indirectly as listed here.
245 127 The independent variables (continuous and categorical) consisted of group,
246 128 gender,age, height, weight, body mass index (BMI), duration of diabetes,
247 129 occupation, Fasting blood sugar (FBS), post-prandial blood sugar (PPBS), HbA1c,
248 130 ankle brachial index (ABI), type of hypoglycemic agent (oral, insulin
249 131 etc),smoking, alcohol, family history, ankle static angle (ASA), ankle heel-strike
250 132 angle (AHSA), ankle toe-off angle (ATOA), knee static angle (KSA), knee heel-
251 133 strike angle (KHSA), knee mid-stance angle (KMSA), knee toe-off angle (KTOA),
252 134 ankle heel-strike velocity (AHSV), ankle mid-stance velocity (AMSV), ankle toe-
253 135 off velocity (ATOV), knee heel-strike velocity (KHSV), knee mid-stance velocity
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284 136 (KMSV), knee toe-off velocity (KTOV), ankle heel-strike acceleration (AHSAA),
285 137 ankle midstance acceleration (AMSAA), ankle toe-off acceleration (ATOAA),knee
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287 138 heel-strike acceleration (KHSAA), knee mid-stance acceleration (KMSAA), knee
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289 139 toe-off acceleration (KTOAA), sensation (touch), ankle reflex, pedal pulse, 10 g
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291 140 monofilament testing, grades of neuropathy (VPT), muscle tightness, dryness of
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293 141 skin, discoloration of feet, toe deformities like hallux valgus, clawing and hammer
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295 142 toes, ingrown nails, callus, fissures, prominent metatarsal heads, peripheral
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297 143 vascular disease, obesity, hypertension, levels of physical activity, vascular and
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299 144 neurological claudication, pedaledema, varicosity, nephropathy ,retinopathy
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301 145 plantar fasciitis ,flexible footwear, rigid footwear ,specialised footwear
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303 146 (micrcellulose rubber), plantar fat pad, max.pressure area, step-time, swing time,
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305 147 double-stance time, gait cycle time, stride time, step-length, gait cycle length, foot
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307 148 angle, foot archtype (cavus/planus), first ray length, fifth ray length, Navicular drop
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309 149 height, foot posture index (FPI), extensor hallucis strength (EHMMT), ankle
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311 150 dorsiflexor strength (ADMMT), plantar flexor strength (PFMMT), knee flexor
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313 151 strength (KFMMT), hip abductor strength (HABMMT), gastrocnemius tightness ,
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315 152 soleus tightness, quadriceps tightness, hip adductor tightness, hip abductor
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317 153 tightness, Illio-tibial band tightness, hamstring tightness, Q angle, Neuropathy
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319 154 scales including Michigan Neuropathy Screening Instrument, Leeds Assessment of
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321 155 Neuropathy Signs and Symptoms, Douleur Neuropathique 4, Neuropathy disability
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323 156 score, Neuropathy Symptoms score respectively (MNSIA, MNSIB, LANSS, DN4,
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325 158 cervicallordosis, kyphosis, lumbar lordosis, scoliosis, pelvis tilt, femoral rotation,
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327 159 genu valgus/varum, patella shift, tibia torsion, and calcaneum neutral. Various sub-
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329 160 analysis were also perform and variables were used. Since it is well known that
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331 161 higher plantar pressure is the most important outcome for predicting diabetic foot

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334 Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
335 Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),
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340 162 syndrome and future ulcerations, we selected peak/maximum pressure as the
341 163 dependent variable.

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344 164 The biochemistry profile for all diabetes mellitus participants were taken from the
345 165 laboratory findings. The clinical assessment for detection of peripheral neuropathy
346 166 was performed as per the standard guidelines using MNSI 10 g Monofilament, and
347 167 VPT testing by a clinician. The muscle strength was determined by the Manual
348 168 Muscle Testing Grading system by a skilled physiotherapist. For kinematic
349 169 analysis 2D/3D SIMI Motion GmbH analysis system was used using two high
350 170 speed infrared cameras and 9 mm retro-reflective marker sets for ankle and knee
351 171 joints [23]. Motion analysis system is the gold standard tool for determining the
352 172 joint kinematics in the current state of art. The kinetic analysis for peak plantar
353 173 pressure was obtained using the Wintrack Dynamic Foot Scanner
354 174 (MEDICAPTEURS Technology France). The data was captured for barefoot
355 175 analysis.

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357 176 Statistical Analysis: The data was analyzed using SPSS15. Multiple regression
358 177 analysis was performed to find the hyperplane of best fit. Stepwise regression was
359 178 performed with ($\alpha_{\text{entry}}=.15$ and $\alpha_{\text{removal}}=.2$) to select the best subset of predictors.
360 179 The predictors in the final model had Variance Inflation Factor less than 5 which
361 180 confirms the absence of possible multicollinearity between predictors. Comparison
362 181 of neuropathy subjects at various grades with non-neuropathy subjects as reference
363 182 have been performed by Wald t test and reported in the table with p values.

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367 183 **RESULTS:** The multiple linear regression analysis for prediction of maximum
368 184 plantar pressure was performed. The descriptive data for blood profile and
369 185 anthropometry has been shown in Table 1 below. Table 2 represents the duration
370 186 of diabetes mellitus and severity grading among the neuropathy group of

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Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),

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395 187 participants. Table 3 represents the estimation of maximum plantar pressure using
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397 188 the regression model.
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400 189 **Table 1: Descriptive for Anthropometric and Blood profile of all Participants**
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VARIABLES	GROUP	GENDER	MEAN±S.D
AGE in years	NEUROPATHY (n =190)	OVERALL MALE (145) FEMALE (45)	57.65±10.77 58.98±10.56 50.60±10.17
	NON-NEUROPATHY (n=190)	OVERALL MALE (142) FEMALE (48)	53.12±10.36 53.65±10.24 50.51±10.61
HEIGHT in cm	NEUROPATHY (n =190)	OVERALL MALE (145) FEMALE (45)	164.57±8.22 167.36±6.13 152.5±4.44
	NON-NEUROPATHY (n=190)	OVERALL MALE (142) FEMALE (48)	164.98±8.55 167.4±6.97 154.19±5.94
WEIGHT in kg	NEUROPATHY (n =190)	OVERALL MALE (145) FEMALE (45)	71.26±10.62 72.66±10.4 65.16±9.63
	NON-NEUROPATHY (n=190)	OVERALL MALE (142) FEMALE (48)	70.32±10.22 71.09±10.29 67.23±9.24
Body Mass Index (BMI)	NEUROPATHY (n =190)	OVERALL MALE (145) FEMALE (45)	26.35±3.32 25.94±3.63 28.12±4.27
	NON-NEUROPATHY (n=190)	OVERALL MALE (142) FEMALE (48)	25.90±2.13 25.40±3.66 28.26±3.39
Fasting Blood Sugar (FBS) in mg/dL	NEUROPATHY (n =190)	OVERALL MALE (145) FEMALE (45)	194.25±66.65 193.96±70.34 198.46±48.89
	NON-NEUROPATHY (n=190)	OVERALL MALE (142) FEMALE (48)	158.43±48.43 159.4±51.73 152.26±32.17
Post Prandial Blood Sugar (PPBS) in mg/dL	NEUROPATHY (n =190)	OVERALL MALE (145)	276.63±74.41 278.47±78.34

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446 Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
447 Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),
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		FEMALE (45)	285.43±55.18
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191 **Table2. Duration of diabetes and severity of neuropathy among DPN group.**

Parameters	Frequency (N %)	
Duration of Diabetes with Neuropathy	1-5 years	56(29.47%)
	6-10 years	63(33.15 %)
	11-15 years	38 (6.7%)
	16-20 years	19 (20%)
	21-25 years	07 (3.68%)
	26-30 years	06(1.1%)
	>31 years	01 (0.52%)
	TOTAL	190(100%)
Grades of Neuropathy (Vibration Pressure Threshold Testing)	MILD	43 (22.63%)
	MODERTAE	57 (30%)
	SEVERE	90 (47.36%)
	TOTAL	190 (100%)

192 **Table 3. Maximum Plantar Pressure Prediction: Parameter estimates using regression**

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Predictors	Estimates	t value	P value	95% Confidence Interval		Partial Eta Squared
				Lower Bound	Upper Bound	
GRADES NEUROPATHY						
MILD	168.758	16.806	< 0.001	149.035	188.482	.337
MODERATE	184.611	17.817	< 0.001	164.258	204.963	.364
SEVERE	186.004	19.656	< 0.001	167.416	204.591	.410
NORMAL
VARICOSITY						
YES	17.751	2.809	0.005	5.340	30.162	.014
NO
PLANTAR CUSHION						
POOR	19.724	4.356	< 0.001	10.830	28.617	.033
FAIR	-3.239	-0.683	0.495	-12.558	6.079	.001
GOOD

Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),

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KMSA (°)	-1.106	-2.574	0.010	-1.950	-0.262	.012
NSS	5.354	4.330	0.000	2.925	7.782	.033
FOOTANGLE (°)	1.049	2.427	0.016	0.200	1.898	.010
KTOAA (°/s²)	0.032	2.844	0.005	0.010	0.054	.014
KTOV (°/s)	0.276	0.059	< 0.001	0.161	0.392	.038
AHSV (°/s)	0.735	0.176	< 0.001	0.390	1.081	.031

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195 *KMSA- knee midstance angle, *NSS- neuropathy symptoms score, *KTOAA- knee toe-off acceleration,
196 *KTOV- knee toe-off velocity, *AHSV- ankle heel strike velocity.

197 Adjusted R² of the final model which included the predictors in table 1 was 90.8%
198 The linear prediction equation obtained using regression analysis is
199 ***Predicted Maximum Plantar Pressure= 504.14 + 186 Severe Neuropathy***
200 ***+184.61 Moderate Neuropathy + 168.76 Mild Neuropathy + 17.75 Varicosity+***
201 ***19.72 Poor plantar cushion-3.24 Fair plantar fat pad - 1.11 KMSA + 5.36 NSS +***
202 ***1.05 Foot angle+0.03 KTOAA+0.28 KTOV+0.74AHSV***

203 ***Here, the predictors such as, Severe Neuropathy, Moderate Neuropathy, Mild***
204 ***Neuropathy, Varicosity, Poor plantar cushion and Fair plantar cushion are***
205 ***indicator variables (they take value 1 for presence and 0 for absence)***

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Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),

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DISCUSSION:

The clinical evaluation and clinical assessment of diabetic foot could help to reduce the risk of future foot complications. The present study highlights that many clinical parameters interact with each other alter the plantar pressure significantly, further damaging the foot and increasing the risk of ulceration among diabetes mellitus. The strength of our study lies in the number of variables assessed and to the best of our knowledge none of the published studies have reported so many variables in a single study with a regression equation.

In the present study, we found a regression model which included kinematics and spatiotemporal parameters gait parameters in addition to neuropathy, vascular, musculoskeletal and other clinical findings against the Maximum Plantar pressure. The results from Table 3 suggested that variables like grades of neuropathy, presence of varicosity, plantar fat pat thickness , knee mid stance angle (KMSA, angle at knee joint during the midstance phase of gait cycle), Neuropathy Symptoms Score (NSS) , Foot angle (degree of toe-out or line of progression), Knee toe-off acceleration (KTOA, acceleartion at knee joint during toe-off phase of gait cycle), Knee toe-off velocity(KTOV,velocity at knee joint during toe-off phase of gait cycle) and ankle heel strike velocity (AHSV, velocity at ankle joint during heel strike phase of gait cycle) are significant predictors of maximum plantar pressure. The coefficient of determination (R^2) for the model is 0.908 which suggests that 90.8 % of variability in maximum pressure is explained by the predictors in the model. The overall F value for model adequacy was observed to be $F(12,568)=469.45$, with a corresponding singnificant *p value* < 0.05. Table3 also

Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),

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619 238 provides the parameter estimates based on which the linear prediction equation has
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621 239 been developed. The equation could be explained as below:
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624 240 The equation suggested that grades of neuropathy had a significant impact on
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626 241 maximum plantar pressure. The regression analysis showed that effect size (partial
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628 242 eta square) increased with an increase in the grade of neuropathy. It should also be
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630 243 noted that severe neuropathy could increase the maximum plantar pressure by
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632 244 186kPa (Table 3) as compared to subjects without neuropathy. Similarly, the poor
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634 245 plantar fat pad in the feet could lead to increase of maximum plantar pressure by
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636 246 19.72kPa whereas a fair fat pad could decrease it by 3.23 units as compared to
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638 247 good fat pad thickness. In the present analysis, variables like knee as well as ankle
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640 248 velocity and acceleration contributed significantly to the prediction model. It is
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642 249 observed that elevated values of knee toe-off velocity, acceleration, and ankle heel
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644 250 strike velocity lead to an increase in the maximum plantar pressure whereas
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646 251 increase in knee midstance angle decreases maximum plantar pressure. In other
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648 252 words, the greater the knee extension, the lower would be the maximum plantar
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650 253 pressure. In the present study, we find that participants with diabetes peripheral
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652 254 neuropathy had higher knee flexion angle at mid-stance. Findings from the present
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654 255 study supports that various clinical parameters could be responsible for increased
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656 256 maximum pressure which could increase the chances of future foot ulceration
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658 257 among neuropathy group. The model has highlighted the significance of varicosity
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660 258 in the lower limb suggesting that peripheral pooling of blood (collection of blood
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662 259 in the lower limb and reduced blood flow from extremity to the heart) in the feet
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664 260 could increase the maximum plantar pressure by 17.75kPa as compared to subjects
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666 261 without varicosity. The results of the present study are similar to the regression
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668 262 model proposed in the previous literature. However, it should be carefully
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670 263 understood that these models could be affected by choice of variables, the

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264 population characteristics, choice and the number of independent variables. To the
265 best of our knowledge, this could be the first study to propose the Diabetic Foot
266 prediction model with more than 150 variables among the Indian population.
267 Ahroni et al. showed that high plantar pressure in diabetic population could be
268 predicted with clinical parameters like body mass, insulin use, Caucasian race,
269 gender (male), callus and diabetes duration [13]. In the present study, body mass
270 was not retained in our clinical model. Cavanaugh et al. also suggested that body
271 mass was a poor predictor [14]. However, results on gender and diabetes duration
272 were in consensus with the previous finding and suggested that female gender
273 showed decreased max. pressure by 19.18 kPa at initial analysis but not retained in
274 the final model .The results of the present study is also supported by findings of the
275 study done by Barn et al. which reported that clinical factor like gender, body
276 mass, diabetes duration, HbA1c, VPT, foot ray (biomechanical axis of the ankle
277 joint), foot deformity, ankle range of motion and callus were significant predictors
278 of peak pressure among 167participants [15]. Similar findings were also reported
279 by Fawzi et al. in the Egyptian population [16]. Few studies with regression
280 analysis on gait kinetics and kinematics have been reported previously. For instance,
281 the study done by Wrobel et al. suggested that in the multivariate analysis for gait
282 parameters age, ankle joint mobility, and callus were retained in the model with
283 17% variance for peak plantar pressure [17]. In the stepwise method, age showed
284 8.23 % variance; ankle joint mobility showed 3.4% and callus showed 1.4 %
285 variance. On the other hand, a study done by Guldmond et al. suggested callus
286 and toe deformities as relevant predictors of peak forefoot pressure with 26 % of
287 the variance [18] .Similarly, the study done by Barn et al. suggested that Charcot
288 foot showed the highest predictor value for peak pressure (Beta coefficient=0.504)
289 [15] . In the forefoot, prominent metatarsal head showed the highest contribution
290 of 31 % followed by claw toes. In the present study, we excluded Charcot foot
Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),

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732 291 however the findings were consistent with prominent metatarsal heads and clawing
733 292 of toes at early stage of analysis. However these factors were not retained in the
734 293 final model. The study done by Fawzy et al. [16] suggested that multivariate
735 294 logistical regression analysis for ulceration risk was statistically significant for
736 295 duration of diabetes (odds ratio [OR] = 0.8), smoking (OR = 9.7), foot
737 296 deformity(OR = 8.7), MNDS (OR = 1.5), 2-h postprandial plasma glucose (2 h-
738 297 PPG) (OR = 0.9), glycated hemoglobin (HbA1c) (OR = 2.1), forefoot peak plantar
739 298 pressure(FFPPP,OR = 1.0),and forefoot peak plantar pressure gradient (FFPPG
740 299 ,OR = 1.0).The study done by Al-Rubeaan et al. reported that the risk factors like
741 300 Charcot's joints, peripheral vascular disease, neuropathy, diabetes duration \geq 10
742 301 years, insulin use, retinopathy, nephropathy, age \geq 45 years, cerebral vascular
743 302 disease, poor glycemic control, coronary artery disease, smoking, and hypertension
744 303 was strongly associated with diabetic foot complications [19]. Also the present
745 304 clinical model is in consensus with the previous findings with the addition of few
746 305 more variables. For e.g., the thickness of plantar fascia or plantar fat pad could be
747 306 an important clinical factor for prediction of peak pressure and future risk of
748 307 ulceration among participants with diabetes [20].The mechanical properties of
749 308 plantar soft tissue can be used to improve the predictability of diabetic foot ulcers
750 309 in moderate/ high-risk patients [21].

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768 310 From the present study, it is evident that the given regression model for diabetic
769 311 foot prediction could be an important tool in day to day clinical evaluation for
770 312 predicting the maximum plantar pressure and minimizing future foot
771 313 complications. Therefore future studies should be done to test the model. Studies
772 314 have reported a threshold values for peak plantar pressure. The study from
773 315 Armstrong et al. reported that a pressure of 60 N/cm² is the upper threshold for
774 316 development of an ulcer in diabetes mellitus [22]. The study also reported a cut-off

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782 Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
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788 317 point of 335 kPa (peak plantar pressure) was considered as a risk, for ulceration at
789 318 forefoot [22]. However, findings from recent studies have been contradictory. The
791 319 study done by Bus et al. suggested that plantar pressure threshold should not be
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793 320 considered as the suitable method for detecting the risk of foot ulceration in
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795 321 participants with diabetes [23]. Nevertheless, the higher plantar pressure in the
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797 322 presence of sensory and motor neuropathy could be a potential risk for foot
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799 323 ulceration [24] . Thus, higher plantar pressure could be significantly associated
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801 324 with deformities and soft tissue changes in the foot. Findings from the present
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803 325 study could help to strengthen the importance of plantar pressure threshold values
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805 326 with future experimental studies.

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807 327 **Future Scope:** The use of the given model could be useful and easier with
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809 328 advanced biomechanical labs with motion analysis. However it could also be
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811 329 extended to communities with 2D video analysis through Smartphone's and freely
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813 330 available software's for video analysis to calculate joint angle, velocity and
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815 331 acceleration. For instance the angular velocity could be obtained by rate change of
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817 332 angular displacement (radians). Similarly, angular acceleration could be obtained
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819 333 by the rate change of angular velocity. The study could be useful to carry out
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821 334 plantar pressure analysis in a clinical population even in the absence of advanced
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823 335 3D motion analysis system using clinical parameters. However, future studies need
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825 336 to work out more on the proposed model which could be more user friendly at
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827 337 clinical and community levels.

828 338 **CONCLUSION:** The suggested model was found be strongly significant in
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830 339 determining the maximum plantar pressure which could be associated with risk of
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832 340 future foot complications. The study highlighted the most important clinical
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834 341 parameters while assessing a diabetic foot with neuropathy. Based on the findings
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836 342 remedies to control plantar pressure could be suggested and rehabilitation protocol

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838 Diabetes peripheral neuropathy (DPN), Diabetic Foot Syndrome (DFS), Ankle
839 Brachial Index (ABI), Ground Reaction Force (GRF), Body Mass Index (BMI),
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843 343 could be prepared. We believe that the given model is in its primary stage and
844 344 future modifications could be required to make it more efficient and user friendly
845 345 for routine clinical practice.

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849 346 **Acknowledgement:** I am grateful and would like to acknowledge World Diabetes
850 347 Foundation project -WDF (15-941)-Stepping Ahead & Centre for Diabetes Foot-
851 348 care and Research, MAHE for all the support provided towards recruitment of the
852 349 participants.

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'Conflict of interest: none'