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Standardization of Foot Sizes of Patients with Diabetic Foot Ulcer through Anthropometric Survey

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ABSTRACT Plantar pressure off-loading at ulcer site is one of the therapeutic interventions for healing diabetic foot ulcer (DFU). Due to peripheral neuropathy and vascular disease, the foot anatomy of patients with diabetes is significantly different from that of normal persons. Presently, the therapeutic footwear or other off-loading devices for patients with DFU are customized which will ultimately delay the treatment intervention. The objective of the present paper is to derive standardized foot anthropometric data for patients with DFU to use as a reference for developing pressure off-loading devices. The measurement of foot dimensions for 100 patients with DFU and 52 age matched control subjects were recorded using 3D laser foot scanner and statistically analysed using SPSS software. By regression analysis, the significant difference and correlation between normal and patients with DFU were studied. By using cluster analysis, 3 average sizes for male and 3 average sizes for female that can accommodate seventy percent of patients with DFU had been derived. Development of pressure off-loading devices based on the derived sizes and trial with patients are on-going projects of this study.

INTRODUCTION

Among the other complications of diabetes, foot complication plays the major role. Foot ulcer is the major cause for patients with diabetes for getting admitted to hospital (Pinzur et al. 2005). One of the main risk factor for amputation in Brazilian population was presence of ulcer (Mantovani et al. 2016). Every 30 seconds one foot is amputated somewhere in the world because of DFU (Bakker et al. 2005). Off-loading devices like ankle foot orthosis (Hanft et al. 2011), rocker bottom shoes (Hanft et al. 2011), removable cast walkers, felted foam half shoes and air cast shoes (Viswanathan and Narayana Rao 2013) are used as a treatment aid for DFU. Presently, the therapeutic footwear or other off-loading devices for patients with DFU are customized (Bus et al. 2011) which ultimately delays the treatment intervention. To make the offloading devices available off-the-shelf, the size of the lower limb (below knee) and foot need to be known. It is then possible to use a proper fitting orthotic device. If the proportionate scaling of instep measurement with foot length is used for designing footwear for normal persons then it may not be ideal for an ergonomic fit. This is due to the poor relationship between arch height and foot length (Hill et al. 2017). Thus, conventional shoe sizing system may not provide proper fitting even for normal population. So there is a need to understand the foot dimensions of persons with DFU in order to prescribe a proper fitting footwear or off-loading device. It is a known fact that persons with diabetes have broader feet than normal subjects (Chantelau and Gede 2002). Foot abnormalities like prominent metatarsal head, high medial arch, hammer toe, muscle wasting, joint stiffness, amputation, fissures, nail deformation, ulcers, blisters, skin dryness, sclerosis and dermopathy are frequent in patients with diabetes (Mansour and Dahyak 2008). But the lower limb (below knee) and foot dimensions of persons with DFU are unknown. Changes in foot dimension and presence of foot deformities influence the risk of developing foot ulcer in patients with diabetes (Boyko et al. 1999; Wrobel and Najafi 2010).

In the past works, the foot length and breadth of normal persons and persons with diabetes were studied (Hanft et al. 2011). McInnes et al. (2012) emphasized the need for a standardized

approach to foot length measurement in diabetic peripheral neuropathy population as they use either too short or too long footwear. Spahiu et al. (2015) studied more parameters of the whole body and foot using 3D laser scanner. These papers are concerned more about the upper body measurements and only two measurements like ankle girth and knee girth were included with respect to lower limb in their study. Sarghie et al. (2013) studied the foot anthropometric data of 23 normal male subjects in the age group of 30-40 years using 3D foot scan, where about 20 parameters were measured and analyzed statistically. There is no such database of anthropometric data of patients with DFU available so far. The researchers' have collected foot anthropometric data of patients with DFU and analyzed statistically to derive standardized sizes for developing off-loading devices.

Objectives

The aim of this paper is to collect and understand the foot anthropometric data of patients with DFU. This data would help in standardizing the size of the diabetic foot having active ulcer. In this work, parameters like the length of the foot, breadth of the foot, ball girth, joint girth, instep girth, ankle girth, heel girth, calf height and calf circumference of patients with DFU are measured and analyzed statistically. Studying the dimension of the ulcerated foot will help in finding out the standard sizes for fabrication of off-loading devices for patients with DFU.

METHODOLOGY

Subjects

The patients with DFU who visited the Podiatry Department of MV Hospital for Diabetes and Research were included in this study. The study involved 100 subjects with 70 male (Age 60.0 ± 8.7 years, Duration of Diabetes 15.7 ± 9.5 years) and 30 female (Age 57.3 ± 9.3 years, Duration of Diabetes 15.6 ± 8.9 years). The employees of various departments of CSIR – Central Leather Research Institute were included for control category. The control subjects include 43 male (Age 53.28 ± 9.42 years) and 9 female (Age 55 ± 2.12 years). Patients were requested to read, understand and sign the consent form before the measurements were taken. The demographic data of subjects is given in Table 1.

Table 1: Demographic data of subjects

S. No.	*Parameter*	*DFU (100)*	*Control (52)*
1	Age (years)	59.33 ± 8.95	53.58 ± 8.62
2	Height (cm)	163.87 ± 9.64	162.31 ± 9.10
3	Weight (kg)	70.27 ± 12.74	65.04 ± 9.86

Foot Survey I

The patient's history of diabetes, age, height and weight were recorded from the hospital record. The measurement of the foot for 100 patients with DFU and 52 normal (Non- diabetes) persons of equal age group were recorded using 3D laser foot scanner (I-Ware Laboratory's INFOOT USB High Type, Model: IFU – H – 01) (Suresh Kumar et al. 2015). Criteria of normal (Non-diabetic) persons were the absence of foot pain or any other complaints, foot deformity and gait abnormality. The collected foot dimension data from the foot scanner included foot length, breadth, ball girth, waist girth, instep girth, heel girth, ankle girth, calf height and calf circumference. The measured dimensions are defined below.

Foot length: The distance from back of the heel to the tip of the longest toe parallel to the long axis of the foot.

Foot breadth: The maximum horizontal distance across the foot perpendicular to the long axis.

Ball Girth: The region around metatarsophalangeal joint.

Waist Girth: The smallest girth behind the ball girth.

Instep Girth: The smallest girth passing over prominence on middle cuneiform.

Heel Girth: This region is the seat to the lowest crease in front of the ankle.

Ankle Girth: This region is around and above ankle bones.

Calf height: The distance between the rear edge of heel and the calf muscle measured at the highest circumference of the calf muscle.

Calf Circumference: The region around the maximum volume of the calf muscle.

All the measurements and patient's information were recorded in the data sheet and fed into the computer using Microsoft Excel worksheet for statistical analysis. The data obtained were analyzed statistically using SPSS software and

the tools such as analysis of variance (ANOVA), regression analysis and cluster analysis. Regression analysis is a statistical tool for the investigation of relationship between variables. Cluster analysis generates groups which are similar. The groups are homogeneous within themselves and as much as possible heterogeneous to other groups. From the analysis, three average sizes for male and female were obtained. The results were compared with Indian Standard Specification for sizes and fitting of footwear IS: 1638-1969.

Validation of Measured Foot Dimensions

A second foot survey was done to check and validate the statistically derived foot sizes. This survey was also done at the Podiatry Department of MV Hospital for Diabetes and Research. A total of 19 patients (Male - 9; Female - 10) participated in this survey.

RESULTS

The mean, standard deviation and significance between left side and right side of various parameters measured from experiment group and control group are given in Table 2. The values given are computed using ANOVA test. From Table 2, it was observed that there was no significant difference between the left foot and right foot among DFU and control group. The length and girth measurements of foot namely; length, breadth, ball girth, instep girth, heel girth and ankle girth measurements are considered to identify the significant difference between left foot and right foot using ANOVA. Later, when the linear regression graphs were plotted between related parameters like length vs. breadth, the correlation between any two parameters of right foot differs from that of the left foot.

The regression coefficients of both DFU and control group are given below in Table 3 and Table 4. The correlation was not significantly symmetric between left and right for DFU group (Table 3) whereas it was somewhat symmetric for normal population (Table 4) except length vs. breadth correlation in normal female population. This may be due to the very small sample size in normal female group.

Table 3: Regression coefficients for DFU group

	Male (R^2)		*Female (R^2)*	
	Left	*Right*	*Left*	*Right*
Length vs breadth	0.34	0.199	0.401	0.061
Breadth vs ball girth	0.674	0.543	0.650	0.111
Length vs calf height	0.218	0.247	0.013	0.074

Table 4: Regression coefficients of control group

	Male (R^2)		*Female (R^2)*	
	Left	*Right*	*Left*	*Right*
Length vs breadth	0.4195	0.3919	0.2892	0.4772
Breadth vs ball girth	0.9008	0.9327	0.8467	0.9674

The Pearson's coefficient of length and breadth shows that the correlation is moderately positive for both DFU (r=0.493 for right and r=0.716 for left) and normal group (r=0.607 for right and r=0.670 for left).

Regression Analysis

It is observed from the measurement that the anatomical difference between left and right feet

Table 2: Mean, standard deviation and significance between left and right foot parameters of DFU and control group

S. No.	*Parameters*	*DFU group*			*Control group*		
		Left	*Right*	*Significance between left and right*	*Left*	*Right*	*Significance between left and right*
		Mean (SD)			*Mean (SD)*		
1	Foot length (cm)	25.52(1.63)	25.40(1.56)	.801	25.09(1.46)	25.04(1.42)	.735
2	Breadth (cm)	10.21(0.92)	10.08(0.89)	.530	10.51(0.75)	10.24(0.74)	.062
3	Ball girth (cm)	23.87(1.90)	24.09(2.19)	.777	25.30(1.47)	25.00(1.58)	.319
4	Instep girth (cm)	26.72(2.43)	26.82(2.17)	.454	25.02(1.37)	25.21(1.51)	.500
5	Heel girth (cm)	33.49(2.83)	33.41(2.33)	.975	34.71(4.75)	34.36(2.84)	.642
6	Ankle girth (cm)	26.12(2.59)	26.49(2.32)	.240	27.06(2.57)	26.75(2.56)	.547

of patients with DFU is not statistically significant. In female subjects (n=30), the correlation between breadth and ball girth of the left foot is given by y=1.746x+5.900, R^2=0.650, which is better than the correlation between length and breadth of left foot with y=0.333x+1.513, R^2=0.401. In male subjects (n=70), the correlation between breadth and ball girth of the left foot is given by y=2.013x+3.360, R^2=0.674. The correlation between length and breadth of the left foot is given by y=0.277x+3.263, R^2=0.34. The regression graph between the length of the left foot and its corresponding calf height shows a poor correlation with R^2=0.013 in female subjects. The regression graph between the length of the left foot and its corresponding calf height shows a poor correlation with R^2=0.218 in male subjects. Thus, it is observed that breadth vs. ball girth is correlated in a better way than that of length vs. breadth. Also, the correlation between length vs. calf height is poor. The R^2 values of diabetic subjects and normal subjects are shown in Tables 3 and 4.

The R^2 values of regression graphs for normal population (Table 4) reveal that the length and breadth are better correlated in male population than female. This correlation may be because of small sample size in the normal female category. Also, the correlation between breadth and ball girth in the normal subjects is better than the DFU subjects. These results confirm the significant difference in girth measurement of patients with DFU.

Cluster Analysis

Instead of averaging the measurements, cluster analysis of data was done to segregate the sizes according to the relationship between the measurements. The mean value of cluster 1 in all the parameters corresponds to size 1. The mean value of cluster 2 in all the parameters corresponds to size 2. The mean value of cluster 3 in all the parameters corresponds to size 3. The mean values for left and right foot for all the three sizes for female and male were tabulated in Tables 5 and 6 respectively.

The clustered three sizes of both male and female were subjected to one-way ANOVA and multiple comparison tests to find the significant difference between the three sizes. The ANOVA test results are given in Table 7. The results show

Table 5: Standardized foot sizes – Female

Parameters	*Size I*		*Size II*		*Size III*	
	Left	*Right*	*Left*	*Right*	*Left*	*Right*
Length (cm)	22.95	23.37	23.72	23.68	24.82	24.59
Breadth (cm)	9.20	9.03	8.90	9.00	9.90	10.04
Ball girth (cm)	21.62	21.83	21.3	21.67	23.70	23.75
Waist girth (cm)	21.50	21.83	21.00	21.58	22.90	23.50
Instep girth (cm)	25.00	25.50	23.33	23.92	26.00	26.55
Heel girth (cm)	30.42	30.42	29.50	30.00	32.45	33.00
Ankle girth (cm)	23.75	24.25	23.00	24.08	25.70	26.55
Calf height (cm)	33.50	33.33	31.33	31.17	33.70	33.50
Calf circumference (cm)	38.83	39.17	31.83	32.17	36.35	35.75

Table 6: Standardized foot sizes – Male

Parameters	*Size I*		*Size II*		*Size III*	
	Left	*Right*	*Left*	*Right*	*Left*	*Right*
Length (cm)	25.34	24.94	25.87	26.05	26.96	27.08
Breadth (cm)	9.44	9.76	10.26	10.54	11.12	11.06
Ball girth (cm)	22.50	22.63	24.11	24.45	26.00	26.41
Waist girth (cm)	22.50	22.67	23.58	23.92	26.25	26.03
Instep girth (cm)	25.50	25.79	26.37	27.24	29.44	29.56
Heel girth (cm)	32.33	32.38	33.63	33.66	36.50	36.50
Ankle girth (cm)	24.08	25.17	26.32	26.66	28.75	28.84
Calf height (cm)	34.17	35.17	35.37	35.21	35.69	35.63
Calf circumference (cm)	33.33	34.13	35.42	35.74	38.88	39.00

Table 7: Significance between three sizes of male and female with respect to each parameter

Parameter	*Significance between 3 sizes*	
	Female	*Male*
Length	0.009	0.005
Breadth	0.004	0.008
Ball girth	0.025	0.001
Instep girth	0.014	0.004
Heel girth	0.005	0.000
Ankle girth	0.043	0.007

that there exists significant difference between all the three groups with respect to each parameter.

Confidence interval chart for foot measurements was determined statistically using SPSS. The ninety-five percent confidence interval for each foot measurement arrived. Confidence interval chart for one of the parameter is given in Figure 1. From the Figure 1, it can be seen that the confidence interval varies for each size and each parameter taken. The confidence interval charts show that there is a difference between each cluster. The confident interval can be increased by increasing the number of data for statistical analysis.

Validation of Measured Foot Dimensions

In case of male patients, it was found that 3 out of 9 patients fall under size I group, three patients fall under size II and remaining three patients have their feet measurements distributed over all the three sizes. In the case of female patients, 4 out of 10 patients fall under size I category and three patients fall under size III. Among the remaining three patients, two of them have their measurements in both sizes I and size II whereas one patient has a foot measurement which does not fall under any of the standard sizes.

DISCUSSION

The mean and standard deviation of 9 parameters which was measured in this work show that there was no significant difference between left and right, whereas the results of linear regression show that there exists an important difference between left and right of DFU patients (Table 3). In a previous anthropometric study by Spahiu et al. (2015), 20 parameters were measured which includes length, breadth, height,

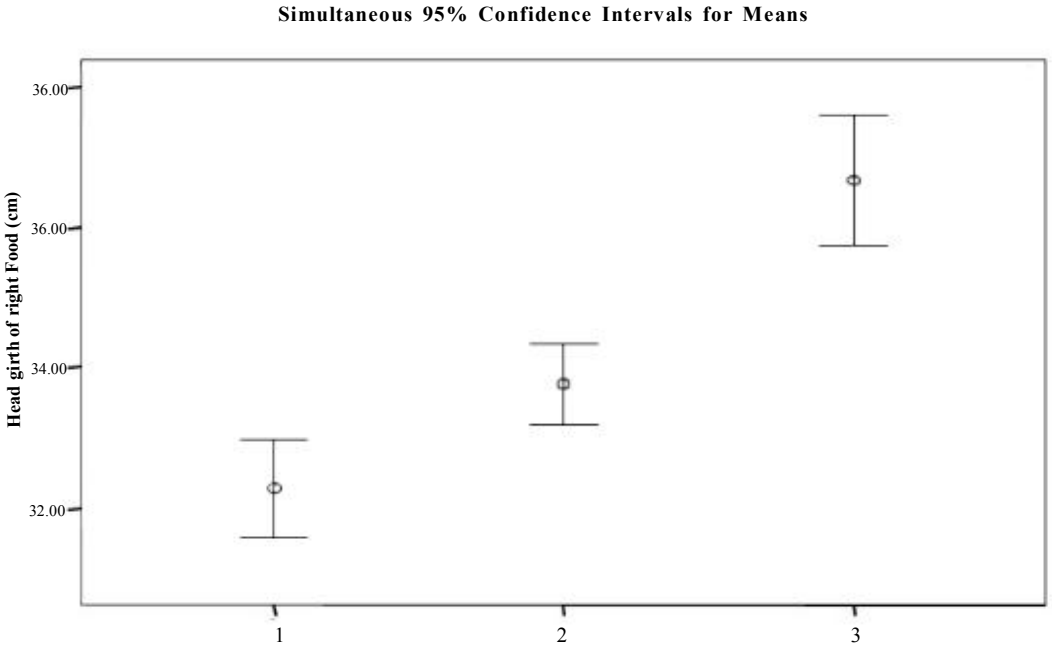

Fig. 1: Cluster Analysis - Confidence interval chart for the right foot's breadth parameter of male subjects

circumference, girth and angles involved in the foot using 3D foot scanner where the results showed that there was no significant difference between left and right foot measurements.

IS 1638-1969 Vs. Derived Standardized Sizes for Patients with DFU

IS 1638-1969 is the Indian standard specification for sizes and fitting of footwear. The English, American and Paris point are widely used sizing systems for making conventional footwear. The English size ranges from 1 to 12 for adults and 1 to 13½ for children. The Paris size varies from 33 to 47 for adults and 18 to 33 for children. The American size ranges from 2½ to 13½ for adults and 1 to 13½ for children. The size interval in English and American size is 8.5mm whereas for Paris point it is 6.6mm. According to IS 1638, there are six categories under which all the sizes will fall (Indian Standard Specification for sizes and fitting of footwear IS: 1638-1969). The categories are infants, children, boys and girls, youths and maids, women and men. The researchers have considered the sizes of women and men for comparison purpose because the experiment population's age group will match better with this category. As per the standard, men fall under size 5 to 11 of English size and women fall under size 2 to 7 of English size. The corresponding English and French sizes with respect to the length measurement for the three standardized sizes derived from patients with DFU are given in Table 8.

Table 8: Corresponding English and French sizes with respect to the length measurement

Standardized size	*Corresponding English size*		*Corresponding French size*	
	Male	*Female*	*Male*	*Female*
Size I	6	3	39	36
Size II	7½	4	41	37
Size III	8	6	42	39

Human feet differ not only in length but also in its volume, that is, for the same length, thin feet, fat feet and normal feet do exist (Mohan Kumar and Sadiq 1999). According to Indian Standard Specification for sizes and fitting of footwear, there are five fittings for each size (Indian Standard Specification for Sizes and Fitting of Footwear IS: 1638-1969). The fitting is represented in letters for English size and numbers for French size. The fittings and its description are given in Table 9.

Table 9: Fitting available for each English size and French size

Description	*Symbol (Letter) for English size*	*Symbol (Number) for Paris Point*
Very small	E	5
Small	F	6
Medium	G	7
Large	H	8
Extra large	XH	9

Considering the significant girth measurements like ball girth, instep girth, heel girth and ankle girth the following things are observed:

Male Sizes

The ball girth of size I fall under G fitting of both size 4½ and 5; size II falls under XH fitting of both 5½ and 6; size III falls under XH fitting of sizes 8½ and 9.

The instep girth of size I falls under XH fitting of size 6 and H fitting of size 7; size II falls under XH fitting of sizes 7 and 8½; size III does not fall even under XH fitting of size 12 (which is the maximum size of the chart, that is Instep girth of 293mm whereas instep girth derived for size III is 294.5mm and 295.6mm).

The heel girth of size I fall under G fitting of size 1; size II falls under F fitting of size 3; size III falls under F fitting of size 7.

The ankle girth of size I fall under XH fitting of sizes 7 and 9; size II falls under XH fitting of size 11 and 11½; size III does not fall under any size (maximum ankle girth in the chart is 269mm whereas the derived size III has an ankle girth of 287.5mm and 288.4mm).

Female Sizes

The ball girth of size I fall under H fitting of size 2 and 2½; size II falls under H and G fitting of sizes 2½ and 3; size III falls under XH fitting of size 4½.

The instep girth of size I fall under XH fitting of size 5 and 6; size II falls under H and XH fitting of size 3; size III falls under H and XH fitting of size 7½.

The heel girth of size I and II does not fall under any of the sizes in the standard chart; size III falls under E and F fitting of size 2½.

The ankle girth of size I fall under XH fitting of size 6½ and 7½; size II falls under XH fitting of sizes 5½ and 7; size III falls under XH fitting of size 10 and 11½.

When comparing the girth measurements of patients with DFU with that of standard sizes, it was observed that 63.2 percent (male) of girth measurements belong to XH fitting which implies that most of the DFU patients have broader feet which were already reported in a study by Chantelau and Gede (2002). According to Chantelau and Gede (2002), the foot length of persons with diabetic polyneuropathy match well with the size of regular footwear available in the market whereas more than two third of the feet were effectively broader than the normal footwear available. The standard sizing system says that G is the average fitting for Indian population. From the results, it was found that three standardized sizes of the male have 63.2 percent of XH fitting, and three standardized sizes of the female have 52.4 percent of XH fitting. Further, male standardized sizes have 15.8 percent of G fitting, 10.5 percent of F fitting and 5.3 percent of H fitting. The female standardized sizes have 4.8 percent of each E, F and G fitting; 23.8 percent of H fitting.

Proportional Measurements of Last

Last is the base for any footwear as it is the replica of the foot. The last has the critical measurements of foot required for making footwear. The derived standard sizes for DFU subjects are ultimately going to be used for making off-loading devices like ankle foot orthosis which require a lower limb mould. So, we need to compare the proportional measurements of conventional last with our derived dimensions for understanding the foot dimensions of patients with DFU.

The proportional measurements of last based on the French point system are (Indian Standard Specification for Sizes and Fitting of Footwear IS: 1638-1969), the length of the last (cm) can be measured by multiplying the French point by two and divide by three; The fitting girth or ball girth (cm) is equal to sum of French point and indicative fitting divided by two; The instep girth (cm) is equal to fitting girth added with 0.5 cm; The heel girth (cm) is equal to sum of length of the last and indicative fitting; The ankle girth is equal to the difference between fitting girth and 0.5 cm.

The six sizes derived from statistical analysis of DFU patient's data do not follow the proportionality mentioned above. For example, the girth measurements of standardized sizes are greater than the actual girth measurement of the size it should possess which indicates that DFU patients do not have their girth measurements matching to the normal foot measurements. The proportionality followed in the conventional sizing system was not observed within the standardized sizes. This disproportion shows that DFU patients cannot go with the conventional shoe sizing system, and they need a separate sizing system to fit in.

CONCLUSION

The three standardized sizes for male and female patients with DFU derived from this study show that they have broader feet and larger girth measurements than normal subjects. These standardized sizes will be useful for fabricating off the shelf offloading devices like ankle foot orthosis and therapeutic footwear which in turn help to save the time taken for making customized foot mould and offloading device. The time interval between prescription of an offloading device and initiating the treatment will be less if the offloading devices are readily available in India in standardized sizes for male and female patients with DFU.

RECOMMENDATIONS

This work can be further extended by taking anthropometric survey of more number of patients to derive few more sizes that can accommodate maximum percentage of people.

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METRIC SYSTEM

1. Length: cm – Centimeters; mm – Millimeters
2. Mass: kg - Kilogram

ABBREVIATION

DFU – Diabetic Foot Ulcer
SD – Standard Deviation

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