INTRODUCTION

The foot is the most inferior part of the human body. The foot makes humans capable of walking, and also perform countless other activities.

The foot’s complex structure involves more than 100 tendons, ligaments, and muscles. They move nearly three dozen joints while bones provide solid base structure. According to the structure of the foot is analogous to that of the hand, but because the foot carries more weight, it is stronger and less active. By wearing ill-fitting shoes, which are not biomechanically friendly, there is a large possibility for the onset of foot problems. A customized insole is mainly used to reduce the abnormal pressures, off-load the pressures equally in the plantar region and protect the formation of foot ulcers. The abnormal pressure regions in the foot is a root cause for the formation of plantar ulcers. Most of these ulcers are developed due to the loss of sensation leading to peripheral neuropathy.

Third leading cause of death is diabetes’s next to heart disease and cancer. According to American Diabetes Association, approximately 15% of patients with diabetes will develop foot ulceration during their lifetime. Lower extremity amputations are mostly preceded by a foot ulcer. “An ulcer can be defined as a breakdown in the skin that may extend to involve the subcutaneous tissue or even to the level of muscle or bone”. These lesions are very common, specifically on the lower extremities. Thus there is a high risk involved, which can lead to many other foot problems.

EFFECT OF FOOTWEAR ON FOOT

According to WHO diabetes program, combined with reduced blood flow, neuropathy (nerve damage) in the feet increases the chance of foot ulcers, infection and eventual lead to limb amputation. Ultimately, there is a great need for foot care. According to the survey taken during a foot camp in Coimbatore, India comprising 96 human populations, about 49.47% of the diabetic population surveyed suffered from foot problems, which showed the least care being given to the lower extremity. Though, diabetic population has a majority of the foot problems, some of the non-diabetic population also has foot problems, which is evident in another research survey taken from a random population during this study.

In the presence of foot problems in normal and diabetic population, foot insoles and footwear play a critical role in the prevention of foot complications. Thus, insoles for people with and without diabetes should not increase the risk of complications, ideally, also serve as a form of safety.

In general, suitable footwear and insoles should:

i. Reduce the abnormal pressures in the plantar region
ii. Limit the formation of ulcers;
iii. Protect from external damages;
iv. Provide proper stability and grip.

Abnormal foot posture and ill-fitting shoes result from structural abnormalities in the foot, and they are not significant when there is no weight lying on the foot. However, when weight is put on the foot during walking and running, the foot has to compensate for any structural defect, in order to achieve forward momentum, or propulsion.
TYPES OF FOOT
Discussing about the foot, foot is classified into three types namely high arch, flat and normal foot' this section provides a detailed outline on the types of foot and their respective load bearing abilities.

High Arch Foot
High arch foot has only a least amount of foot contact surface area on the ground, i.e. toes, ball, heel regions. It may also have a narrow band connecting the fore foot with the heel. It is called as under pronator or over supinator. There will be too much shocks traveling up the legs since arch don’t collapse much to absorb the shock. Hence High arch footers are not excellent shock absorbers32.

Flat Foot
Flat foot has a little or no arch contour, which is also called as excessive pronation. This is due to the fallen arch by well-developed muscles in the plantar area. Lower arches can give rise to stress fractures, tendonitis, heel spurs or plantar fasciitis. After the heel strike is made i.e. after one micro second, the arch collapses inwards too much. The stability of flat foot population is very less, and this can cause an increase in the risk of injuries33.

Normal Foot
Normal foot has a perfect arch contour and is also known as normal and neutral pronator. This is the most common foot type. Normal arches are often biomechanically efficient but still can be susceptible to common foot problems such as heel pain or ball-of-foot discomfort.

From the literature, it is very evident that there is a large possibility for the onset of foot problems in all types of foot, particularly in flat and high arch foot population. Hence foot care is of utmost importance in all these three cases. In order to analyses the peak pressure data with respect to types of foot, there is a need to select a suitable method that would be perfect for further analysis. To select the perfect trial, a methodology has been designed in this paper.

PROCEDURE INVOLVED IN FOOT PRESSURE DATA COLLECTION
Selecting an appropriate trial from a group of pedobarographic data involves a step by step procedure. The patient data were collected and the type of foot was determined by analysing the Contact Area of the foot and the structure of the foot image. Then the logic of selection methodology was carried out in order to exclude the anomalies and select an appropriate trial for further purposes on design.

Step 1 – Collection of patient data
Step 2 – Plantar Pressure measurement
Step 3 – Logic of Selection
Step 4 – Selection of an appropriate trial

DATA COLLECTION
Subjects
Ninety six participants were voluntarily recorded in this research study. No subjects had surgeries undergone within the previous year. The population included three arches namely the normal arch, flat foot and high arch foot. The data were analysed using SPSS software. Table 1 describes the statistical data of foot types, a total of 192 patients’ foot were analysed of which 73.43 % were normal foot, 23.43 % were high arch and 3.14 % are flat foot respectively.

Plantar Pressure Measurement System: Pedobarography
The term ‘PEDOBAROGRAPHY’ is derived from the Latin word ‘pedes’ which means the foot and the Greek word ‘baros’ which refers to ‘weight’ and also ‘pressure’. Hence Pedobography is the study of plantar pressure acting along the interface between the plantar region and the supporting ground14. Measuring the pressure under the foot is useful under some conditions such as diabetic neuropathy and rheumatoid arthritis, which can cause excessive pressure that lead to ulceration. Some diabetic neuropathy patients have pressures of 1000-3000 kPa beneath the foot as a result of abnormal gait patterns15. Plantar pressure measurement techniques are more useful in the analysis and for understanding of the biomechanics of a human foot The Pedobarography also helps to scientifically conclude the foot health. Floor-mounted systems have an array of force sensors. When the subjects walk across the force sensors, the vertical ground reaction force (GRF) in the plantar region is measured. These systems use different kinds of force sensors such as resistive and capacitive strain gauges, conductive rubber and piezoelectric materials.

Hardware Used
Plantar pressure measurement devices fall into two main types: (i) floor-based, and (ii) in-shoe based16. The floor-mounted systems have more accuracy, and more pressure points are obtained when compared to in-shoe devices. The technology used in this research study is a floor based pressure platform named “Emed-A50 platform” which produces both 2D and 3D image time series of the pressures acting under the plantar surface of the foot. From these data other variables such as contact duration, pressure-time integral, and Centre of Pressure trajectory may also be calculated. The Emed-A50 platform consists of 1760 sensors contained in an area of 389 x 226 cm² with a resolution of 2 sensors per cm²17.

Significance of Centre of Pressure Line (Gait Line)
The Centre of Pressure (COP) curve, or gait line can provide more information regarding the foot function and pathology. In biomechanics, centre of pressure (COP), also called the gait line which is the point of application of the GRF vector18. The GRF vector denotes the sum of all forces acting between a physical object and its supporting surface. Analysis of the centre of pressure is common in studies on human postural control and gait. A small change in the walking style or other factors such as footwear used, clothing, etc. may be reflected in changes in the centre of pressure19. The reaction forces vary with a high pressure during heel strike and during the toe-off i.e. push off with fore foot. There are both horizontal and vertical GRF in which the horizontal GRF is very small when compared to vertical GRF20.

Plantar Pressure
Foot forms the primary contact with the ground surface and there is a huge need of care to be given to the plantar region. One good method to measure the foot health is by sensing the pressures in the plantar region of the foot7. These pressures are abnormal in some cases mainly due to pronated or supinated foot. Load distribution analysis showed that the heel carried 60%, midfoot 8%, and forefoot 28% of the weight-bearing load.
The toes were only minimally involved in the weight-bearing process\(^2\). In accordance with the literature, low arched feet have higher pressures on the medial side of foot. Moreover, subjects with a lower arch, i.e. a flat foot have a greater BMI. Hence there is an effect of arch height and BMI on plantar pressure in the foot\(^3\). In common, higher peak pressure is particularly measured at the heel, forefoot and big toe, while the lowest pressures have been observed under the midfoot and toes during dynamic analysis. The high pressures measured at the heel happen in the early stance phase of the gait and also the highest pressures under the metatarsal heads in the late stance of gait\(^4\).

**Pressure Regions and Manual Masking**

By considering the biomechanical, design, manufacturing and ergonomic considerations it would be better to divides the plantar surface into anatomical regions/zones. In general plantar surface of the foot, its size and peak pressures vary among the individuals. Therefore, masking of the plantar surface region and designing the customized insole along with assigning different material to manufacture the customized insole is seen as an option. In order of assigning different materials and for the reason of offloading the pressures exerted in the foot masking is undergone. Manual masking of the normal foot is shown the figure 1, the plantar surface of the foot is masked into five zones, phalanges, metatarsal, midfoot, heel and arch.

**MEASUREMENT OF PLANTAR PRESSURE AND PATIENT DATA**

The Figure 2 describes the steps in the patients data collection, this section provides a detailed step by step procedure involved in patient data collection that is crucial for developing the custom insole. Referring to Figure 2, in the first stage 1, data alike; age, height, weight, BMI and body fat composition were recorded using Karada Scanning System from the selected population. At stage 2, patients walk on the Novel Emed platform from which their plantar pressure data are recorded. At this stage a visual inspection is made on the trials to make sure the data was captured appropriately. At the end of this stage a complete set of data is obtained for further evaluation. Eight trials were recorded per person i.e. four trials on each of the foot.

In Figure 2, stage 3, for the obtained four trials per foot, manual masking is undergone such that it would aid for better selection of the foot based on pressure value distribution and surface area of contact. Stage 4, a crucial stage which adopts a specific logic of selection. From the measured trials, selection is based by analyzing the following parameters:

1. Abnormal gait pattern is excluded.
2. Gait pattern ambiguity at the toe off and heel strikes are excluded.
3. Peak pressure consistency and total contact area of contact is analyzed.
4. Abnormal peak pressures in comparison to trial obtained data are excluded.
5. Individual zone peak pressures for left and right are analyzed.
6. Pressure distribution pattern was analyzed, and exclusions are made.

At this stage the plantar pressure data results were taken for visual inspection and are masked into regions, which included phalanges, metatarsal, midfoot, heel and arch. These masked regions are compared for variations in each trial of the foot. Following the comparison finally obtained result would be the plantar pressure data taken for precise analysis of plantar pressure of the foot.

**Comparison of the Trials on Left Foot**

Comparison of the two trials is shown in the Figure 3, as discussed in the earlier section, six exclusion criterion are used to select the final pressure points data for designing the customized foot insole. The criterion includes; (i) abnormal gait pattern, (ii) gait pattern ambiguity (that occur between heel strike and toe off), (iii) peak pressure consistency and total contact area, (iv) Abnormal peak pressure (erratic changes in peak pressure), (v) individual zone peak pressure and (vi) Uniform pressure distribution pattern. For a clear understanding, table II gives the comparison indicator for the logic of selecting suitable trial, were (i) rounded rectangle represent the abnormal gait pattern, (ii) ellipse represent the gait pattern ambiguity, (iii) rectangle represent the peak pressure consistency and total contact area, (iv) circle represent the abnormal peak pressure and (v) thumbus represent the uniform pressure distribution pattern.

Comparison of the four trials is shown in the figure 4, in the figure 4a abnormal peak pressure consistency and pressure distribution pattern is found, in figure 4c abnormal gait pattern, peak pressure consistency and total contact area, abnormal peak pressure and pressure distribution pattern were found, in figure 4d abnormal gait pattern, gait pattern ambiguity, peak pressure consistency and total contact area.

**Inferences from Comparing Trials on Left Foot**

A total of four trials performed on each foot, and the same are compared according to the logic of selection criteria. The comparison of different trials is shown in the table III, the inference found during comparison involves:

- On comparing the four trials, there is an abnormal gait pattern, i.e. Centre of Pressure line, in the third and fourth trial in the metatarsal region.
- The fourth trial shows more ambiguity in the gait pattern i.e in the Centre of Pressure line during the heel strike and the toe-off condition.
- The third and fourth trial shows a vast variation in contact area, and so these extremes are being excluded. In both first and second trials, clearly the gait pattern is smooth and the peak pressure lies in the metatarsal region. Whereas in the third and fourth trial the peak pressure lies in the hallux region, also known as the phalanges. Since there is a gait pattern ambiguity the peak pressure must have risen in these trials and therefore; last two trials are excluded.
- Due to an abnormal gait pattern in the third and fourth trial, there is an abnormal peak pressure distribution of 565 and 410 kPa respectively. Following which, these two trials are excluded.
- The pressure distribution pattern is found different in the trials a, c and d. There is an irregular pressure distribution pattern in the mid-foot region of the first and fourth trial, which excludes these trials. Furthermore, there is an abnormal pressure pattern found in the metatarsal and heel region of the third trial, figure 4. So the third trial is also excluded a detailed description is also provided in table III.
- Following the above logic of selection, the finally obtained data set is the second trial data, and the same is selected for the design of the custom orthotic insole.

Thus selection of the appropriate data set is carried out by following the logic of selection methodology, which excludes the abnormal peak pressures, abnormal gait pattern, improper pressure patterns, and ambiguities at heel strike and toe off conditions.
Table I: Statistical data on foot types

<table>
<thead>
<tr>
<th>Type of foot</th>
<th>No. of foot</th>
<th>% of foot type</th>
</tr>
</thead>
<tbody>
<tr>
<td>High arch foot</td>
<td>45</td>
<td>23.43</td>
</tr>
<tr>
<td>Flat foot</td>
<td>6</td>
<td>3.125</td>
</tr>
<tr>
<td>Normal foot</td>
<td>141</td>
<td>73.43</td>
</tr>
</tbody>
</table>

Table II: Comparison indicator

<table>
<thead>
<tr>
<th>S.No</th>
<th>Logic of Selection</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Abnormal gait pattern</td>
<td>Rounded Rectangle</td>
</tr>
<tr>
<td>2.</td>
<td>Gait pattern ambiguity</td>
<td>Ellipse</td>
</tr>
<tr>
<td>3.</td>
<td>Peak pressure consistency and total contact area.</td>
<td>Rectangle</td>
</tr>
<tr>
<td>4.</td>
<td>Abnormal Peak Pressures</td>
<td>Circle</td>
</tr>
<tr>
<td>5.</td>
<td>Individual zone peak pressures for left and right.</td>
<td>Visual Comparison</td>
</tr>
<tr>
<td>6.</td>
<td>Pressure distribution pattern.</td>
<td>Rhombus</td>
</tr>
</tbody>
</table>

Table III: Comparison table on the four trials-left foot

<table>
<thead>
<tr>
<th>Parameters</th>
<th>AB GAIT</th>
<th>GAIT AMB</th>
<th>CONTACT AREA (cm²)</th>
<th>PP ZONE</th>
<th>PP kPa</th>
<th>AB PP</th>
<th>PR PATT</th>
<th>TOF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left foot</td>
<td>X1</td>
<td></td>
<td>156.5</td>
<td>M</td>
<td>345</td>
<td>X</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>S2</td>
<td>X</td>
<td></td>
<td>155.5</td>
<td>M</td>
<td>380</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>X3</td>
<td>X</td>
<td>X</td>
<td>152</td>
<td>HA</td>
<td>565</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>X4</td>
<td>X</td>
<td>X</td>
<td>159.5</td>
<td>HA</td>
<td>410</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

AB GAIT- Abnormal Gait, AB PP - Abnormal Peak Pressure, GAIT AMB - Gait Ambiguity, PP ZONE - Peak Pressure Zone, PR PATT - Pressure distribution pattern, CONTACT AREA - Total area of contact, TOF – Type of Foot, N – Normal Foot, F – Flat Foot, H – High Foot, S – Selected Trial, X – Rejected Trial, M – Metatarsal, HA – Hallux, HE – Heel.

Figure 1: Zone Splitting of Plantar Surface
Collecting patient data using Karada Scanning System

8 trials are recorded with 4 trials from each foot using Novel Emed platform

Selection of the best trial by Logic of Selection

Masking into regions for precise analysis

Figure 2: Steps in patient’s data collection

Figure 3: Comparison of the two trials on the left foot stating the reasons for exclusion
CONCLUSION

Gait analysis is used to measure and evaluate the dynamic and static gait patterns. In this work, along with gait analysis, a subject’s pressure point distribution along with his foot loading conditions during static and dynamic motions are analysed. When it comes to analysis and selection of the right data set, understanding the research gap involved in a logical selection procedure. This research made an attempt in framing the logical framework that can be used for selection of the best data set from the obtained trial / sample datas. Thus, from the number of trials recorded using the pressure platform, a perfect trial was selected, as discussed above. Hence a perfectly recorded trial involves,

- No abnormal gait pattern.
- No ambiguity at heel strike and toe off.
- No abnormal peak pressures.
- No abnormality in pressure regions and contact area.
- Consistency in the peak pressure’s values.
- Considerations made on both the foot.

From this analysis possible design input such as peak pressure and corresponding shore hardness values for the split orthotic insole; number of masked regions, size and shape of the foot for insole dimensioning can be obtained for the design and development of orthotic insoles.

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