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Original Article

Using Manchester Scale classification of Hallux Valgus as a valuable tool in determining appropriate risk categorization during initial diabetic foot screening in primary health care settings

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ABSTRACT

Limitations have been identified in the current state of primary care practises with regards to identifying and correctly categorizing foot deformity and its associated risk of developing foot ulcers in patients with diabetes. This study aims to bridge these gaps through the implementation of additional categorization tools to be made available for primary care professionals. This study thus analysed the relationship between foot pressure distribution and amount in patients with diabetes with Hallux Valgus foot deformity, and its different stages, in order to better understand the clinical applications of the Manchester Scale. Statistically significant data in pressure distribution ($P < 0.05$) was found in all three severity groups identified by the Manchester Scale (Mild, Moderate and Severe) when compared to a No deformity group. However, only the Severe Hallux Valgus group crossed the threshold over 500 kPa in the area of first metatarsal bone. Further research should aim to analyse pressure distribution and amount in patients with both diabetes and diabetic neuropathy of all stages of Hallux Valgus.

1. Introduction

The global prevalence of diabetes mellitus in 2012 was 371 million people [1]. By 2035 this number is expected to rise two-fold, with diabetes mellitus affecting a projected 600 million people [2]. Primary health care professionals have already begun to see sharp increases in the number of patients with diabetes mellitus entering their offices. Paramount to handling this growing epidemic is developing quick and inexpensive tools to accurately and effectively identify patients that may be prone to long-term complications from diabetes, including foot complications. By quickly identifying at-risk of developing foot complications from diabetes, ulcers and consequential foot amputations can be properly mitigated by primary health care professionals during their first screening [3].

According to the Riber GE study [4], there are three main key indicators associated with the development of diabetic foot ulcers – peripheral neuropathy (present in 78% of cases), minor trauma (present in 77% of cases) and foot deformity (present in 63% of cases). Likewise, the International Working Group on the Diabetic Foot (IWGDF) provides additional links between the presence of peripheral neuropathy along with foot deformity, peripheral arterial disease, and history of ulcers or amputation. The IWGDF recommends increases in frequency of patient care, staging this care according to co-presence of these factors [5]. It is clear then, that appropriately identifying peripheral neuropathy, foot deformity, and the presence of other factors is drastically important to determining patient care.

Inlow's 60-Second Diabetes Foot Screen (Fig. 1), as the frequently used assessment tool, draws attention to various parts of the foot that together indicate risk-levels of developing foot complications. Inlow's Foot Screen looks at skin, nails, deformity, footwear, circulation and neuropathy and has excellent interrater and intrarater reliability, along with good predictive validity [6]. While Inlow's Foot Screen provides clear margins for assessing neuropathy and minor trauma, there is a noticeable discrepancy between risk indications that might arise as a result of developing foot deformity. Likewise, the distinguishing difference between mild, moderate and severe foot deformity is unclear. According to IWGDF, the presence of foot deformity together with neuropathy moves at risk diabetic foot from category 1 (Intermediate

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Risk) to category 2 (High Risk) [5]. As such, the subjective and unclear nature of the assessment of foot deformity leaves patients at risk for mis-categorization. Linking between the stage of foot deformity to pressure distribution and pressure amount, under the diabetic foot during walking, would provide additional information that would better aid the appropriate categorization of a patient's condition, and establish their subsequent treatment plan [7–9].

The majority of diabetic foot ulcers present in the forefoot area, at an estimated 77% in all diabetic patient cases [10]. The most frequent forefoot deformity is Hallux Valgus, with a recent study positioning it at a 23% global prevalence rate among 18−65 year olds, with an upwards climb to 35% for those 65+ [11]. As a result of these two covariant factors, along-side the above stipulated shortcomings of current assessment tools, this study aims to investigate the ways in which different stages of the Hallux Valgus deformity affects foot pressure distribution and amount in the diabetic population, in order to better assess, categorize and treat this group within primary care facilities.

2. Methodology and study design

2.1. Determining assessments for initial recruitment

In accordance with best clinical practises, the primary health care professional's assessment of the foot, and any subsequent identification of deformity, should occur during the initial screening within the primary care facility. Thus, practicality and efficiency are important to the assessment protocol's feasibility. The appearance and stage of deformity to the Hallux Valgus is generally assessed through the use of serial radiographs; with the noted difficulties of implementation within primary care settings, an alternative method was explored for determining Hallux Valgus deformity. The Manchester Scale provides an apt solution to these clinical limitations, as series of photographs, incrementally

INLOW'S
60-second Diabetic Foot Screen
SCREENING TOOL

Canadian Association of Wound Care — Association canadienne du soin des plaies
www.cawc.net

Patient Name: Clinician Signature:
ID number: Date:

Look – 20 seconds	Score: Left Foot	Score: Right Foot	Care Recommendations
1. Skin 0 – intact and healthy 1 – dry with fungus or light callus 2 – heavy callus build up 3 – open ulceration or history of previous ulcer			
2. Nails 0 – well-kept 1 – unkempt and ragged 2 – thick, damaged, or infected			
3. Deformity 0 – no deformity 2 – mild deformity 4 – major deformity			
4. Footwear 0 – appropriate 1 – inappropriate 2 – causing trauma			
Touch – 10 seconds	**Left Foot**	**Right Foot**	**Care Recommendations**
5. Temperature – Cold 0 – foot warm 1 – foot is cold			
6. Temperature – Hot 0 – foot is warm 1 – foot is hot			
7. Range of Motion 0 – full range to hallux 1 – hallux limitus 2 – hallux rigidus 3 – hallux amputation			
Assess – 30 seconds	**Left Foot**	**Right Foot**	**Care Recommendations**
8. Sensation – Monofilament Testing 0 – 10 sites detected 2 – 7 to 9 sites detected 4 – 0 to 6 sites detected			
9. Sensation – Ask 4 Questions: i. Are your feet ever numb? ii. Do they ever tingle? iii. Do they ever burn? iv. Do they ever feel like insects are crawling on them? 0 – no to all questions 2 – yes to any of the questions			
10. Pedal Pulses 0 – present 1 – absent			
11. Dependent Rubor 0 – no 1 – yes			
12. Erythema 0 – no 1 – yes			
Score Totals =			

Screening for foot ulcers and/or limb-threatening complications. Use the highest score from left or right foot.
Score – 0 to 6 → recommend screening yearly
Score – 7 to 12 → recommend screening every 6 months
Score – 13 to 19 → recommend screening every 3 months
Score – 20 to 25 → recommend screening every 1 to 3 months

Comments:

1 Adapted from Inlow S. A 60 second foot exam for people with diabetes. *Wound Care Canada*. 2004;2(2):10-11. · © CAWC 2011 · 101E

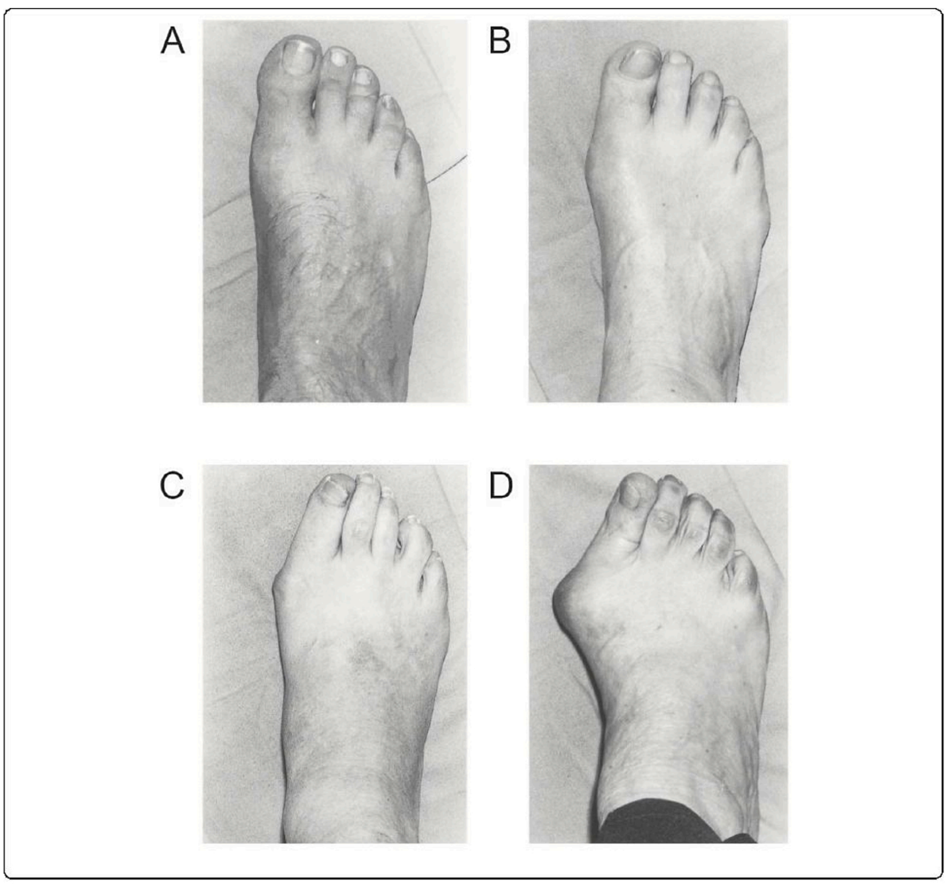
Fig. 1. Inlow's 60 – second Diabetic Foot Screen.

showcasing the stages of foot deformity (from none, mild, moderate to severe) which are then matched with the patient's foot. The Manchester Scale has been shown to have high intraster and intertester grading reliability of the Hallux Valgus and provide a high degree of accuracy when matched with categorization determined by radiography [12,13].

For this study we created a laminated page, with a series of photographs illustrating the different stages of Hallux Valgus deformity in accordance with the Manchester Scale (Fig. 2) and distributed it to two primary health care providers that utilize Inlow's Foot Screen during their patient assessments. During the examination of the foot, health care providers filled out a form indicating the patient's stage of Hallux Valgus. This form accounted for additional factors that might influence both the pressure distribution and amount under the foot of a diabetic patient, allowing us to narrow our study scope to exclude these factors, and focus specifically on assessing the pressure patterns associated with the Hallux Valgus.

Within these exclusionary factors, we chose to narrow our criteria according to the primary deformities that can impact pressure distribution significantly. Namely, this included additional qualification criteria that assessed the impact and state of deformities of the Hallux Limitus [14–19] and Ankle Equinus [14,20–22]. Hallux Limitus deformity is divided into five stages according to the passive assessment of the hallux dorsiflexion (DF) in the first metatarsophalangeal joint [23]. For our study, we included only patients that presented with no-Hallux Limitus deformity (DF $> 60^\circ$) and those at stage 0 (DF $40-60^\circ$). Stages 1,2,3 and 4 were subsequently marked as exclusionary factors. Stage 0 was included because, during normal gait, only 70–80% of ROM in 1st PMPJ is used while 20% as measured during passive assessment is not used [24]. For patients presenting with Ankle Equinus deformities, we excluded those with less than 0° of dorsiflexion in the ankle joint, during the non-weight bearing examination. After research consultation it was noted that the ankle joint in a diabetic patient during gait went from 0.2° of dorsiflexion to 5.6° of plantar flexion [25]. Those with less than 0° of dorsiflexion would thus impact pressure distribution derivative from deformity to the ankle joint.

Additional research has indicated that pressure distribution and amount is significantly impacted in patients with peripheral sensory input is reduced, such as those with sensory neuropathy [26,27].



A NORMAL

B- MILD

C- MODERATE

D- SEVERE

Fig. 2. Manchester Scale for Hallux Valgus used as the Visual Tool.

Utilizing the Semmes Weinstein monofilaments, patients with peripheral neuropathy were also excluded from the study. Additional qualifying exclusion criteria was scoped to include patients with any history of foot surgery, foot amputation, use of walking aids, previous or current existence of foot ulcer(s), rheumatoid arthritis, history of gout, or any neurological condition since these conditions may significantly alter the biomechanics of gait, and subsequent pressure distribution under the patient's foot.

2.2. Study population

In accordance with the above-stipulated screening forms, 630 diabetic feet in DAFHT's primary care setting were screened and their forms filled by two chiropodists. When the exclusion criteria were applied, 183 diabetic feet were selected. The DAFHT Research Ethics Committee approved study and all patients gave verbal consent.

Using the Manchester Scale, and additional form to exclude patients with confounding complications that might impede their eligibility, the 183 feet were categorized according to their stage of Hallux Valgus deformity. After processing the forms, 80 feet were determined to have no HV, 59 presented with mild deformity, 25 with moderate deformity, and 19 with severe deformity. All 19 patients categorized as having a severe deformity were contacted for pressure measurements, with 9 agreeing to participation. The 9 patients were matched with patients from the other remaining stages of Hallux Valgus deformity that had similar ages and weights in order to account for pressure variations that might accompany these factors [28,29]. The final study sample included the 9 feet marked with severe Hallux Valgus deformity, 9 moderate, 7 mild, and 8 with no-marked deformity to the Hallux Valgus. Each group's relevant age and weight averages, in pounds (lb), are noted below in Table 1.1.

Through the use of this methodology, we were able to ensure that factors that might otherwise manipulate pressure patterns and measurements were mitigated through the use of exclusionary conditions in the initial stages of patient categorization, and by grouping patients according to similar weight and age. By mitigating factors that might otherwise change pressure patterns, this study aims to assess the difference in pressure patterns as they relate to the different stages of Hallux Valgus deformity exclusively.

Comparing the pressure distribution patterns between diabetic patients with different stages of Hallux Valgus was determined when considering that individuals with diabetes mellitus without any microvascular or macrovascular complications still have different pressure distribution than healthy individuals [30].

2.3. Plantar pressure data collection process and analysis protocol

After patient recruitment and filtering, the plantar pressures of these patients were collected and measured. This process was performed using the TEKSCAN HR MAT (Tekscan Inc., Boston), placed in the centre of a flat walkway, allowing for adequate space to perform regular walking. This mat contains 8448 individual pressure sensing cells and shows moderate to good pressure detection reliability [31]. The frequency was set to 50 Hz during the collection process. The two-step gait initiation protocol was used to obtain pressure data [32]. Each patient received their own pressure recording.

During the initial collection process, the weight of each patient was taken and confirmed, along with their stage of Hallux Valgus deformity. The platform was then calibrated for each participant. Each patient was then instructed to walk across the walkway, including the platform, at their regular speed. After ensuring each patient was comfortable walking across the platform, five trials were recorded for each foot. A trial was repeated in the event the investigator observed atypical foot placement.

Table 1.1
Overview of patient data.

Stage of HV deformity	Number of patients	Average weight	Average age
No deformity	8	162 ± 19.9	68.4 ± 8.2
Mild	7	182 ± 3.4	76.6 ± 8.6
Moderate	9	175 ± 14.8	72.9 ± 11.5
Severe	9	167 ± 15.5	74.9 ± 6.3

2.4. Pressure distribution measurements

After data collection, an average of 5 trials for each foot per participant was performed using original software from Tekscan. Each averaged pressure map was masked in the 12 regions using Tekscan software. These regions are described as follows (Fig. 3):

MH - Medial Heel; LH - Lateral Heel; MF - Midfoot; M1 - Metatarsal Head 1; M2 - Metatarsal Head 2; M3 - Metatarsal Head 3; M4 - Metatarsal Head 4; M5 - Metatarsal Head 5; T1 - Toe1; T2 - Toe 2; T3 - Toe 3; T4/5 - Toe4-5.

The averaged peak plantar pressure (PPP) of each foot region was then allocated to their appropriate Hallux Valgus stage as determined by the initial assessment. Finally, the averaged PPP of each region for each Hallux Valgus deformity stage was obtained. Each pressure analyzed foot was visually inspected to ensure that each region was properly placed, both prior to obtaining pressure readings, and upon analyzing the final image produced by the Tekscan software.

2.5. Pressure amount measurements

Another investigative component of this study aims to assess the threshold of the amount of PPP that might place a diabetic patient in a risk group for developing a diabetic foot ulcer. The current literature contains inconsistent information related to the PPP levels that correspond to the critical range for developing such an ulcer. Taking into consideration the broad scope of the PPP range, this study established a 500 kPa according to the average range utilized by Cavanagh PR [33] which will be explored further within the discussion.

2.6. Statistical analysis

Statistical analysis was performed using IBM's SPSS-24. Selected plantar pressure measurements of 12 regions of the foot for the following distribution categories: 9 Severe Hallux Valgus deformity, 9 Moderate Hallux Valgus deformity, 7 Mild Hallux Valgus deformity and 8 No Hallux Valgus. One-way analysis of variance was employed to assess for significant difference between the No Hallux Valgus group against the remaining three stages of deformity. A standard probability level of $P < 0.05$ was selected. A power analysis was done between the three categories, with percentage chance of Null Hypothesis rejection calculated at 10.3% in the Mild v No group, 5.3% in the Moderate v No group, and 7.4% in the Severe v No group.

3. Results

This study analyzed both pressure distributions and amounts of various stages of Hallux Valgus deformity (Mild, Moderate and Severe) in diabetic non neuropathic populations, and compared them against a group of diabetic patients with No Hallux Valgus deformity identified. PPP distribution was found to be statistically significant in all three groups when compared to the No Hallux Valgus group. Pressure distribution was significantly differential at MF in the Mild Hallux Valgus group, at M5 in the Moderate Hallux Valgus group, and at M1 in the Severe Hallux Valgus group, when compared to the No Hallux Valgus group. A summary of the results for each severity category can be found below according to their respective groupings in Tables 2.1–2.3. With respect to measurements of pressure amount, only one area was found to exceed our critical threshold 500 kPa with significance when compared

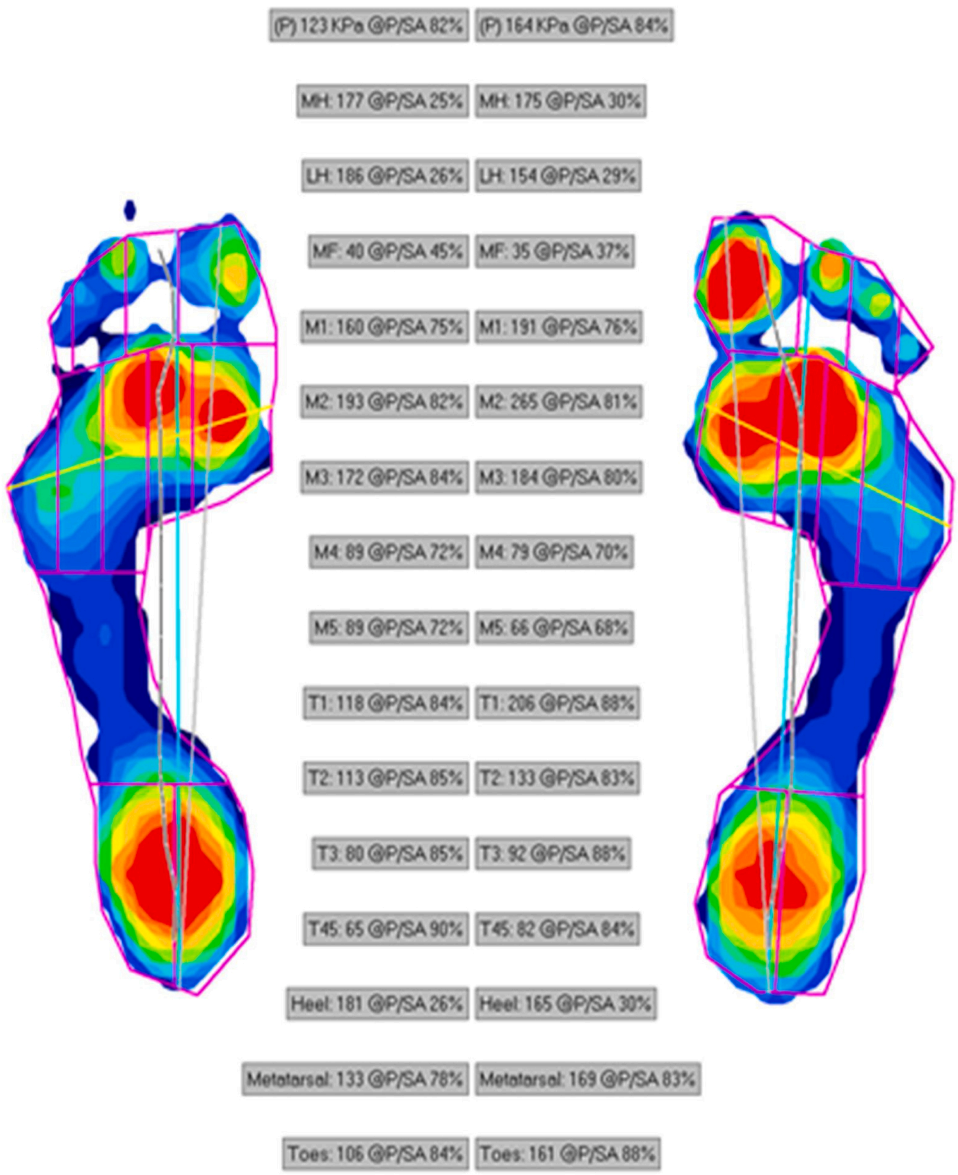


Fig. 3. Averaged Peak Pressure Masking Regions.

Table 2.1
Average NO HV-Mild HV deformity peak plantar pressure.

Area	No HV	Mild HV	Signifcance
MH	380.125	316.4285714	n/s
LH	342.25	261.7142857	n/s
MF	154.5	92.14285714	0.017
M1	442.625	397.8571429	n/s
M2	435.125	400.8571429	n/s
M3	456	391.1428571	n/s
M4	258.25	222.8571429	n/s
M5	175.625	226.2857143	n/s
T1	369	411	n/s
T2	195.25	185.1428571	n/s
T3	123.125	129.1428571	n/s
T45	73.375	62.85714286	n/s

Table 2.2
Average No HV-Moderate HV deformity peak plantar pressure.

Area	No HV	Moderate HV	Signifcance
MH	380.125	342.2	n/s
LH	342.25	304	n/s
MF	154.5	146.8	n/s
M1	442.625	399.7	n/s
M2	435.125	377.3	n/s
M3	456	373.5	n/s
M4	258.25	276.1	n/s
M5	175.625	380.3	0.035
T1	369	386.3	n/s
T2	195.25	187.2	n/s
T3	123.125	141	n/s
T45	73.375	69.3	n/s

to the No Hallux Valgus control group. In the severe Hallux Valgus deformity category, the area of the 1st metatarsal exceeded the critical threshold at 601 kPa.

4. Discussion

4.1. Shortcomings of Inlow's foot screening protocol

The growing epidemic of diabetes mellitus calls for greater attention

Table 2.3
Average No HV-Severe HV deformity peak plantar pressure.

Area	No HV	Severe HV	Signifcance
MH	380.125	352.33333	n/s
LH	342.25	287.55556	n/s
MF	154.5	152.33333	n/s
M1	442.625	601.11111	0.043
M2	435.125	487.11111	n/s
M3	456	438	n/s
M4	258.25	263.33333	n/s
M5	175.625	271.11111	n/s
T1	369	315.22222	n/s
T2	195.25	163.11111	n/s
T3	123.125	151.11111	n/s
T45	73.375	91.333333	n/s

and effectiveness in provisional primary health care. For patients with diabetes mellitus, the risk of developing ulcers and other foot complications is significantly higher than within the lay population. The ability of health care professionals to adequately and accurately provide care rests on the ability to assess and categorize associated risks for each patient. This process is comprehensive and multifaceted, with a variety of factors considered that shape each patient's specific risk and treatment plan. The IWGDF makes clear that adequately assessing various factors such as neuropathy, foot deformity, and accompanying diagnosis, can lead to significant differences in a patient's treatment plan [5].

Inslow's Foot Screen attempts to robustly provide health care professionals with succinct analysis tools to evaluate various factors. Inslow's assess many factors that place diabetic patients at a higher risk of developing foot ulcers including neuropathy, minor trauma, and foot deformity. The neuropathy assessment is well defined, combining both a tactile monofilament test and a series of questions related to a patient's experience of nerve sensation, ensuring the primary health care professional has a comprehensive understanding of the patient's condition. The Foot Screen likewise analyzes the condition of footwear, allowing the practitioner to quickly note discrepancies between the patient's foot and their footwear, in order to account for the impact of minor trauma on the potential to develop further foot complications. However, in determining the state of foot deformity, the Foot Screen falls short. Vague definitions of the stages of foot deformity, as none, mild or severe, makes the subjective nature of this assessment methodology open to potentially significant error that could change a patient's final treatment plan. Considering the relationship between pressure distribution and amount and the stage of Hallux Valgus foot deformity may potentially provide insight into the relationship between the stage of foot deformity and the risk of developing a foot ulcer. This would ultimately ensure higher reliability in categorizing a patient's risk group and subsequent treatment protocol, in accordance with the International Working Group for the Diabetic Foot [5]. While Inslow's Foot Screen does not specify the type of foot deformity measured, this study focuses on Hallux Valgus foot deformity, as it is one of the most frequently occurring deformities in the foot. This study does not specifically apply to other types of foot deformities, which warrant further research.

4.2. Pressure amount determination & evaluation

The amount of pressure that would qualify a patient for an at-risk category was determined to be 500 kPa for the purposes of our study. The literature with regards to the relationship between peak plantar pressure (PPP) and the development of foot ulceration, as mentioned above, is inconsistent. Some authors suggest thresholds that qualify a critical pressure at 875 kPa or 700 kPa, with sensitives of 63.5% and 70% and specificity ranges of 46.3%–65% respectively [34,35]. Others suggest that a threshold of 355 kPa of PPP is sufficient to be considered dangerous, with an accompanying sensitivity of 60% and specificity of 74.3% [36]. Additional literature places the critical threshold between 500 kPa and 650 kPa [33,37–39]. Many authors, however, conclude that the higher the kPa the larger the risk of ulceration for patients with diabetes. In addition to this PPP in healthy individuals shows the highest values in the area of 2nd metatarsal head and this threshold is in the range from 361 kPa [40] to 420 kPa [41]. As such, it would be reasonable given these values, to place peak plantar pressure at a critical threshold within the 500 kPa region and above, especially when considering normal pressure thresholds rest between 361 kPa and 420 kPa. This valuation is in agreement with Cavanagh CR [33], who observed a majority of patients with foot ulcers as having a PPP above this 500 kPa threshold.

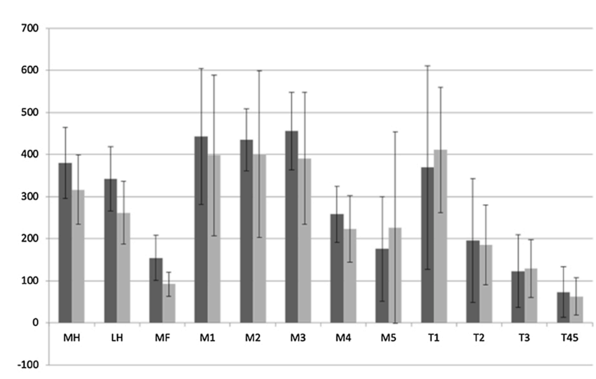
In our study, the group of diabetic patients who have a severe stage of hallux valgus presents above this threshold in the area of 1st metatarsal. This leads us to the conclusion that only patients with severe Hallux Valgus as assessed by Manchester Scale should be considered to have foot deformity of Hallux Valgus in the Inlow's 60-second foot assessment and placed in the High Risk group of patients with diabetes when using IWGDF [5].

4.3. Pressure distribution evaluations

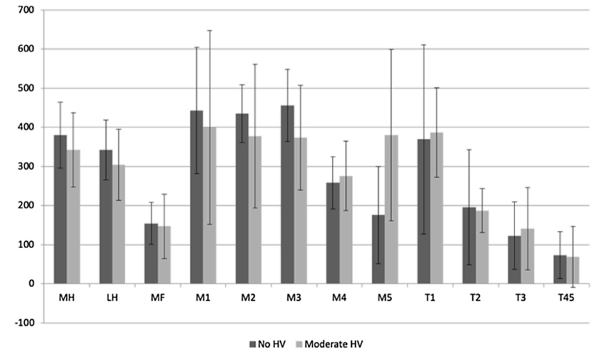
Since Hallux Valgus deformity is a progressive disorder, pressure distribution under the foot can be anticipated to vary in accordance with different stages of deformity [7,42]. Our analysis of pressure distribution considers 3 separate regions of the foot: rearfoot – containing the medial heal (MH), lateral heal (LH) and midfoot area (MF) – the forefoot region – containing 5 metatarsal areas (M1, M2, M3, M4 and M5) – and the toe region's five structures (T1, T2, T3 and 4th and 5th toe grouping T45).

When analyzing the different rearfoot regions during all three stages of Hallux Valgus deformity, it can be noted that overall, all three regions (MH, LH and MF) have a lower pressure average when contrasted against the No Hallux Valgus group. The Midfoot area shows statistically significant differentiation within the Mild Hallux Valgus deformity group when compared to the No deformity category. While not statistically differential, all three-showcase considerable consistency in lower pressure valuations when compared to the No deformity group. This can be observed in Graphs 1.1–1.3.

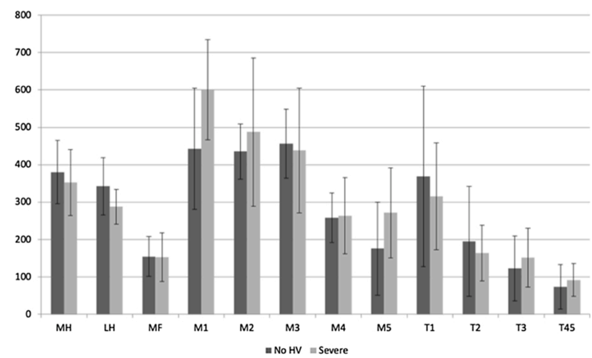
Pressure distribution typically moves from the rearfoot region towards the forefoot in diabetic patients when compared to health individuals. A combination of diabetes mellitus and a foot deformity, such as those of the Hallux Valgus, can cause a decrease in pressure in the rearfoot and transference of such pressure towards the forefoot. This subsequently increases forefoot to rearfoot pressure ratios. These ratios have been shown to provide an excellent predictive tool for assessing risk of developing foot ulcers [38]. In addition to this, a diagnosis of peripheral neuropathy contributes further to increased pressure in the forefoot area [26,27]. It can be considered then that all three mentioned factors, diabetes mellitus, sensory neuropathy and deformity to the



Graph 1.1. Average Peak Plantar Pressure (kPa) measurements compared between No HV and Mild HV deformity categories.



Graph 1.2. Average Peak Plantar Pressure (kPa) measurements compared between No HV and Moderate HV deformity categories.



Graph 1.3. Average Peak Plantar Pressure (kPa) measurements compared between No HV and Severe HV deformity categories.

Hallux Valgus, move pressure from the rearfoot region to the forefoot, thus aggregating the cumulative pressure ratio and subsequently, increasing the risk of foot ulceration [38]. This is in agreement with the previously mentioned Riber study, which highlighted casual pathways for risks associated with diabetic pressure ulceration [4].

When analyzing the peak plantar pressure in the forefoot area, there was no significant difference between the Mild Hallux Valgus deformity group and the group with No deformity present [8]. Furthermore, peak pressure distribution for both groups of participants in the mild and no deformity group align with pressure distribution data of healthy adults, without a diabetes diagnosis [40,41]. However, there are significant changes in pressure distribution patterns in both moderate and severe Hallux Valgus deformity groups. The Moderate group shows a statistically significant increase in pressure in the 5th metatarsal. Research done by Koller U [9] produces similar results, with heightened pressure distribution at the 5th metatarsal region. Koller's study analyzed pressure distribution with a participant pool of 55.6% containing moderate deformities and 9.6% with severe deformities.

Thus, Koller's study provides adequate and important correlation with the results obtained in this study, with respect to pressure distribution for moderate deformity patient categories. However, our study also highlighted statistically significant pressure distribution in the area of the 1st metatarsal head for the severe deformity group, which is in agreement with several studies [15,16,42,43]. This might be as a result of the different functional abilities of the first metatarsal joint in different stages of Hallux Valgus deformity, during the push off phase in regular gait [44]. There are two studies that suggest an increased pressure is present in the central region of the metatarsal in patients with Hallux Valgus deformities [45,46]. However, these studies did not differentiate between different stages of Hallux Valgus deformity and this may critically influence the results. This further emphasizes the necessity to properly categorize and differentiate between the different stages of Hallux Valgus deformity.

When analyzing the toe region, there is higher pressure distribution in the T1 area within the Mild Hallux Valgus group. This did not prove to be a statistically significant differentiation and did not reach the critical threshold of 500 kPa. This is in agreement with the current literature that has analyzed Mild Hallux Valgus deformity and pressure distribution [42,47].

5. Conclusion

This study primarily arose from a need to find additional methods that could better aid primary health care professionals in their ability to identify and determine a risk category for diabetic patients at risk for foot ulceration. Deficiencies in the foot deformity assessment of Inslow's 60 Second Foot Screen were noted, which could significantly alter a patient's treatment plan and program. Through research, the Manchester Scale was potentiated as a viable solution to these shortcomings that could better aid in a professional's ability to identify and appropriately categorize foot deformity severity and its associated risk with foot ulceration in diabetic patients. This study thus analyzed the relationship between foot pressure distribution and amount in diabetic patients with Hallux Valgus foot deformity, and its different stages, in order to better understand the clinical applications of the Manchester Scale. After identifying the severity of deformity to the Hallux Valgus using the Manchester Scale, pressure distribution and amount was measured for each group of severity (No, Mild, Moderate and Severe) and the No group was compared to the remaining three in order to analyze the difference in pressure distribution and amount for each category. The results suggest that within the severe category, pressure readings from M1 would place patients above a critical threshold and into a higher risk category and thus change their future treatment plan. Readings from both Mild and Moderate deformity groups provide additional insight into the changes of pressure distribution that take place during the progression of Hallux Valgus deformity, but do not indicate towards meeting the critical threshold for intervention.

6. Implications for practice

Within primary care settings, accurate and reliable risk categorization of patients at risk for foot ulceration is necessary in order to establish an appropriate treatment plan. Pressure distribution and amount measurements, particularly within diabetic patients with foot deformities, provide a window for primary care professionals to better assess the risk of developing foot ulceration. Within a clinical setting, the practicality of measuring pressure is reduced; however, the Manchester Scale is able to ensure reliable categorization without the need to introduce direct pressure measurements. This study indicates that the relationship between deformity of the Hallux Valgus can be considerably related to pressure distributions and readings, which in turn can streamline the process by which a patient's risk can be more accurately assessed.

7. Limitations

While this study examined the pressure distribution and amount in diabetic patients with varying Hallux Valgus deformities, it did not include patients who had a diagnosis of peripheral neuropathy of any degree. Diabetic patients have a heightened predisposition to the development of neuropathy, and this in turn, could change the pressure amount and its distribution for patients with a presenting Hallux Valgus deformity. Changes in pressure distribution and amount of this variety, in patients with neuropathy present, might result in a reading that would meet or exceed the established critical threshold of 500 kPa. Thus, the risk categorization of patients with neuropathy and Hallux Valgus deformity might be heighted at lower deformity varieties then those without neuropathy. Furthermore, because of the impacts that age and weight may play in pressure amount and distribution, the sample size was limited. While there was a statistically significant relationship in values between all categories of deformity, the significance is tempered by the size of the population sampled.

8. Recommendations for further research

This research study considered only deformities of the Hallux Valgus; further research considering other deformities may better improve risk categorization in Inslow's Foot Screen tool. Considering the exclusion of neuropathy within this study, it is indicated that additional research initiatives should explore the role of neuropathy on the pressure distribution and amount within various stages of Hallux Valgus deformity, in order to analyze and establish a relationship between the factors. Further research should be done with higher sample population sizes in order to account for a higher power value. However, given the limitations imposed by co-variable factors, such as age and weight, both of which were accounted for and played a role in reducing the overall population size, finding larger sample sizes may produce serious difficulties for further research.

Conflict of interest

The authors whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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