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# A COMPARATIVE STUDY ON PRESSURE POINT IDENTIFICATION AND VIBRATION PERCEPTION ASSESSMENT IN DIABETIC PATIENTS USING INNOVATIVE DEVICE AND CONVENTIONAL METHOD

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## ABSTRACT

**Background**: Diabetic peripheral neuropathy is a major microvascular complication of diabetes mellitus and plays a critical role in the development of diabetic foot ulceration and lower limb amputation. Conventional bedside screening tools such as the 10 g monofilament and 128 Hz tuning fork are inexpensive and widely used; however, they are limited by subjectivity and inability to assess plantar pressure abnormalities. An integrated device capable of evaluating both pressure distribution and vibration perception may improve early detection of high-risk diabetic feet.

**Aim**: To compare the diagnostic effectiveness of an innovative pressure point identification and vibration perception device with conventional neuropathy screening methods in patients with diabetes mellitus.

**Methods**: A prospective comparative study was carried out among 100 diabetic patients at the Department of General Surgery, Saveetha Medical College and Hospital. Participants were equally divided into an experimental group assessed using the innovative device and a control group evaluated using conventional techniques including monofilament and tuning fork testing. Clinical findings, neuropathy detection rate, plantar pressure assessment, diagnostic accuracy, usability, and patient comfort were analyzed statistically.

**Results**: The innovative device demonstrated superior neuropathy detection compared with standard bedside methods. Quantitative plantar pressure mapping identified a greater proportion of high-risk pressure zones. The device also showed improved sensitivity, specificity, and overall diagnostic accuracy. Assessment time was shorter, while clinician usability and patient comfort scores were significantly better in the experimental group.

**Conclusion**: The combined pressure and vibration assessment device provided more accurate and objective evaluation of diabetic peripheral neuropathy than conventional screening tools. Early identification of sensory impairment and abnormal plantar pressure may facilitate timely preventive intervention and reduce the risk of diabetic foot ulceration and amputation.

**KEYWORDS:** Diabetic peripheral neuropathy, plantar pressure, vibration perception, diabetic foot, neuropathy screening, innovative diagnostic device

## INTRODUCTION

Diabetic foot disease (DFD) imposes a massive global burden, with an estimated 8.8% of adults worldwide affected by diabetes as of 2017[1]. Lifetime incidence of diabetic foot ulcer (DFU) ranges from roughly 15% to 34%[2], and at any given time about 6.3% of people with diabetes have an active foot ulcer[2]. Alarmingly, up to 85% of diabetes-related lower-extremity amputations are preceded by a foot ulcer[3]. The five-year mortality rate associated with diabetic foot complications (including ulceration and amputation) is extremely high – on the order of 30-50% – comparable to or worse than many forms of cancer[4][5]. For instance, one study reported five-year mortality of 30.5% for patients with DFU and 46-56% after amputation, versus 9% in breast cancer and ~31% across all cancers[4]. The economic costs are likewise staggering: in the U.S. an estimated \$237 billion was spent on diabetes care in 2017, with up to one-third of these direct costs attributable to diabetic foot complications[6]. In Scotland, for example, diabetes care consumes ~£1 billion annually (≈8% of National Health Service expenditure), of which a substantial proportion is related to foot ulcers and amputations[7]. Preventative foot care yields immense cost savings, given that effective ulcer prevention averts hospitalizations and surgeries.

Despite the well-established benefits of prevention, existing screening tools in routine practice are often inadequate or under-utilized. Clinical guidelines (such as those from the International Diabetes Federation and NICE) recommend regular foot screening – typically including visual inspection and a 10-g monofilament sensory test – for all patients with diabetes. However, reliance on monofilament testing alone can miss many at-risk patients. The Semmes-Weinstein 10-g monofilament is a simple and inexpensive tool to assess loss of protective sensation, but its diagnostic accuracy is limited. A systematic review by Dros et al. found monofilament sensitivity ranging from only ~41% up to 93%, with specificity

from 68% to 100% across studies[8]. This variability reflects inconsistent technique and the test's inability to quantify degree of neuropathy. In practice, monofilament exams may be improperly conducted or documented, leading to under-identification of high-risk feet. Moreover, monofilament testing gives a binary outcome (feeling intact or lost) and cannot detect gradual sensory decline or reveal pressure distribution problems.

Elevated plantar pressures are the other "silent" driver of DFU risk, alongside neuropathy. Areas of abnormally high pressure, especially under deformities or prominent metatarsal heads, can precipitate skin breakdown in the insensate foot. Yet plantar pressure measurement is rarely performed in general clinical practice due to lack of accessible devices and the time/cost involved[9]. Traditional pressure-platform systems are expensive and typically confined to specialist centers. Consequently, frontline providers often have no objective data on pressure "hotspots" – limiting their ability to target offloading interventions before ulcers occur. There is a clear rationale for innovation: a need exists for a practical, affordable device that can simultaneously assess the two key risk factors – plantar pressure distribution and vibration sensation – in a single patient-friendly exam. By combining pressure point mapping with a vibration perception threshold test, such an integrated tool could enable early identification of patients at highest ulcer risk (those with the dangerous combination of high pressure and severe neuropathy). This can facilitate timely preventive measures (e.g. therapeutic footwear modifications) and bridge the gap between advanced biomechanics labs and real-world primary care settings.

In summary, the significant morbidity, mortality, and costs associated with DFD[4][5], coupled with the limitations of current screening methods, underscore the imperative for an innovative dual-function device to improve preventative diabetic foot care.

## METHODOLOGY

### Study Design

This study was designed as a **prospective, comparative, analytical study** conducted to evaluate the effectiveness of an innovative pressure point identification and vibration perception device in detecting diabetic peripheral neuropathy, in comparison with conventional methods (10 g monofilament and 128 Hz tuning fork).

### Study Setting

The study was conducted in Patient admitted in **Department of General Surgery in saveetha medical college**.

### Study Duration

The study was carried out over a period of 6 **months** from 01/10/2025 **to** 01/04/2026.

### Study Population

All patients diagnosed with **diabetes mellitus** attending the outpatient or inpatient department during the study period were considered for inclusion.

### Sample Size

A total of **100 patients** were included in the study.

- **Experimental Group (n = 50):** Assessed using the innovative device
- **Control Group (n = 50):** Assessed using 10 g monofilament and 128 Hz tuning fork

The sample size was determined based on feasibility and previous similar studies evaluating diagnostic accuracy.

### Sampling Method

Patients meeting the inclusion criteria were selected using a **consecutive sampling method** and were equally allocated into two groups.

### Inclusion Criteria

- Patients aged **≥18 years**
- Diagnosed cases of **Type 1 or Type 2 diabetes mellitus**
- Patients willing to participate and provide **informed consent**

### Exclusion Criteria

- Patients with **active foot ulcers or infections**
- History of **lower limb amputation**
- Known **neurological disorders** unrelated to diabetes
- Patients with **severe peripheral vascular disease**
- Patients unable to cooperate with examination.

### Ethical Considerations

- Ethical clearance was obtained from the **Institutional Ethics Committee (IEC)** prior to the commencement of the study.
- Written **informed consent** was obtained from all participants.
- Patient confidentiality was maintained throughout the study.

**Study Procedure**
All enrolled patients underwent a detailed clinical evaluation, including:
**Clinical Assessment**
- Detailed history including duration of diabetes, treatment, and symptoms of neuropathy
- General physical examination
- Foot examination for deformities, callosities, and skin changes

**Group Allocation and Assessment**
**A. Control Group (n = 50)**
Patients in the control group were assessed using conventional methods:
1. **10 g Monofilament Test**
- Applied at standard plantar sites (great toe, metatarsal heads, heel)
- Loss of sensation at ≥1 site was considered abnormal
2. **128 Hz Tuning Fork Test**
- Applied over bony prominences (great toe)
- Vibration perception recorded as present or absent

**B. Experimental Group (n = 50)**
Patients in the experimental group were assessed using the **innovative device**, which included:
1. **Pressure Point Identification**
- Measurement of peak plantar pressure
- Assessment of pressure distribution and asymmetry
- Identification of high-risk zones
2. **Vibration Perception Assessment**
- Quantitative measurement of vibration perception threshold
- Objective recording of sensory deficits

**FIGURE 1. FINAL INNOVATIVE DEVICE PICTURE**

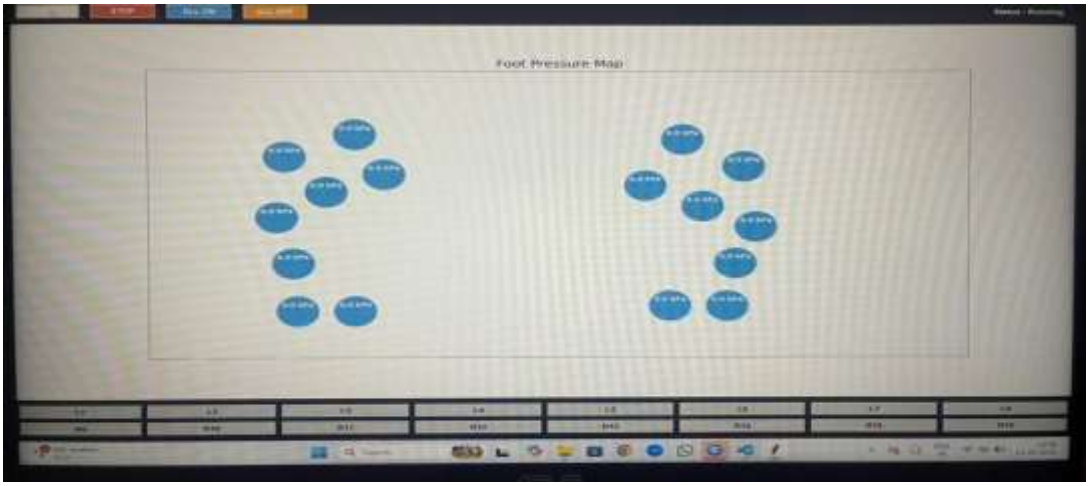



**FIGURE 2. SOFTWARE APPLICATION**

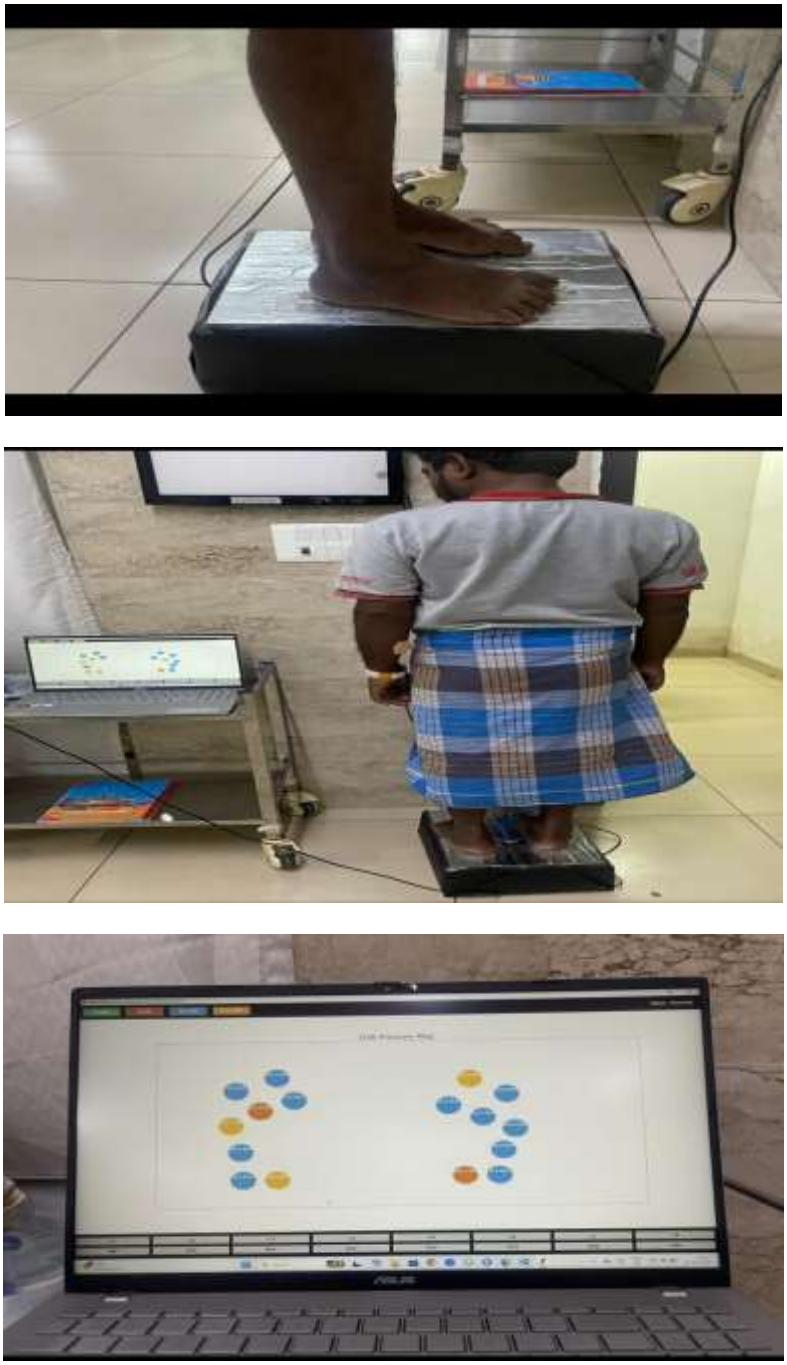
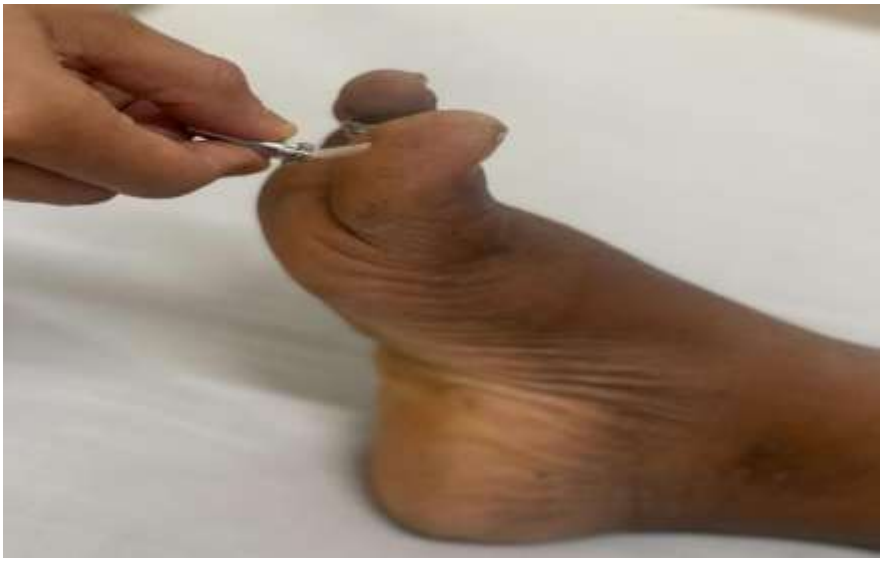


**FIGURE 3. PRESSURE AND VIBRATION PERCEPTION USING INNOVATIVE DEVICE**



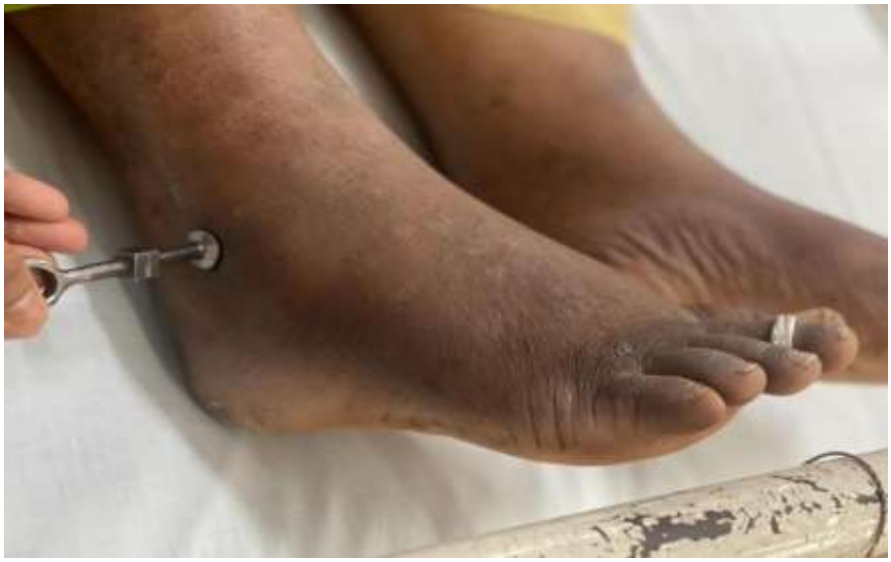


**FIGURE 4. PRESSURE AND VIBRATION PERCEPTION USING MONOFILAMENT & TUNNING FORK**

**Gold Standard for Diagnosis**

Neuropathy status was confirmed using a **combined reference standard**, including:

- Clinical examination
- Vibration perception threshold assessment
- Monofilament testing

This served as the **gold standard** against which both methods were compared.

**Outcome Measures**

**Primary Outcomes**

- Detection of diabetic peripheral neuropathy
- Sensitivity and specificity of diagnostic methods

**Secondary Outcomes**

- Identification of high-risk plantar pressure zones
- Assessment time
- Patient comfort score
- Clinician ease-of-use score

**Data Collection**

- Data were recorded in a **pre-structured proforma**
- Parameters included demographic details, clinical findings, and test results
- All measurements were documented systematically for analysis

**Statistical Analysis**

Data were analyzed using SPSS version 25. Continuous variables were expressed as mean ± SD. Categorical variables were expressed as percentages.

p-value <0.05 considered significant.

**RESULTS**

**1. Baseline Characteristics**

**Table 1 : Baseline characteristics**

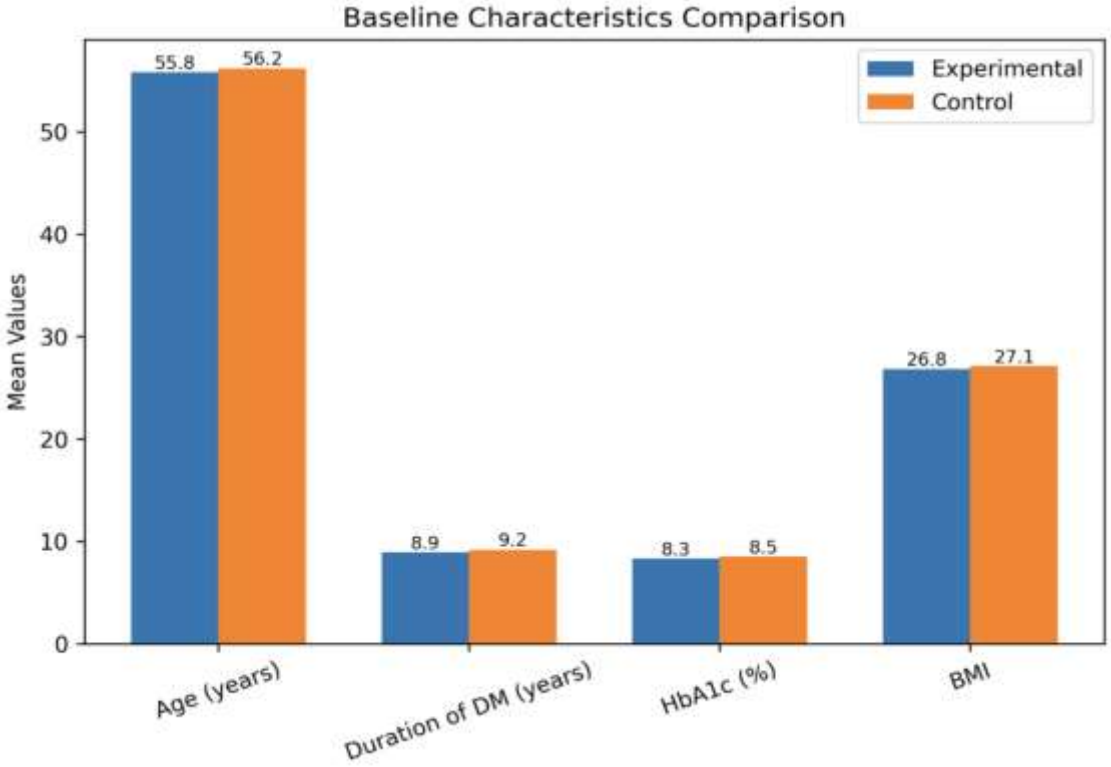
| Variable | Experimental (Innovative Device) (n=50) | Control (Monofilament + 128 Hz Tuning Fork) (n=50) | p-value |
|---|---|---|---|
| Age (years) | 55.8 ± 7.9 | 56.2 ± 8.4 | 0.78 |
| Male (%)<br>Female (%) | 28 (56%)<br>22 (44%0 | 27 (54%)<br>23 (46%) | 0.84<br>0.74 |
| Duration of DM (years) | 8.9 ± 4.1 | 9.2 ± 4.5 | 0.69 |
| HbA1c (%) | 8.3 ± 1.1 | 8.5 ± 1.3 | 0.42 |
| BMI | 26.8 ± 3.4 | 27.1 ± 3.6 | 0.67 |

A total of 100 patients with diabetes mellitus were included in the study and equally allocated into two groups:

- **Experimental group (n = 50):** Assessed using the innovative pressure point identification and vibration perception device
- **Control group (n = 50):** Assessed using conventional methods (10 g monofilament for sensory testing and 128 Hz tuning fork for vibration perception)

The baseline demographic and clinical characteristics of both groups are summarized in Table 1.

**Graph 1: Graph showing baseline characteristics among groups**

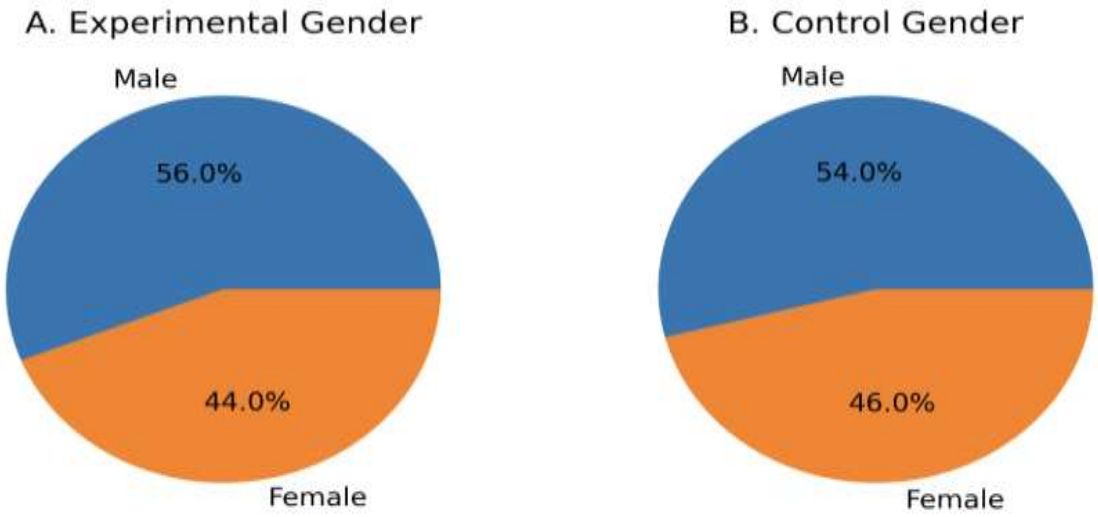



The mean age of patients in the experimental group was **55.8 ± 7.9 years**, compared to **56.2 ± 8.4 years** in the control group (p = 0.78), indicating no statistically significant difference. Male participants constituted **56%** of the experimental group and **54%** of the control group (p = 0.84), showing comparable gender distribution.

The mean duration of diabetes mellitus was **8.9 ± 4.1 years** in the experimental group and **9.2 ± 4.5 years** in the control group (p = 0.69). Glycemic status, assessed by HbA1c, showed mean values of **8.3 ± 1.1%** and **8.5 ± 1.3%**, respectively (p = 0.42), indicating similar levels of glycemic control.

Body mass index (BMI) was also comparable between groups (**26.8 ± 3.4 vs 27.1 ± 3.6; p = 0.67**).

**Graph 2: Graph showing gender distribution among groups**



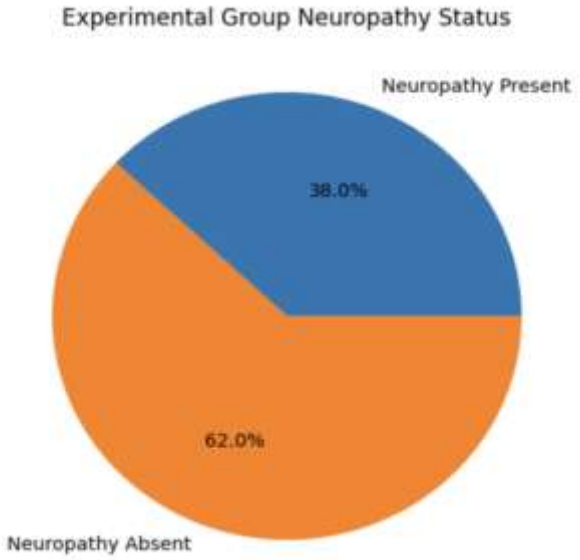
Overall, there were **no statistically significant differences (p > 0.05)** in baseline variables, confirming that the two groups were well matched and suitable for comparative analysis.

**2. Gold Standard Neuropathy Status**

| Parameter | Experimental | Control | p-value |
|---|---|---|---|
| Neuropathy Present | 19 (38%) | 18 (36%) | 0.83 |
| Neuropathy Absent | 31 (62%) | 32 (64%) | — |

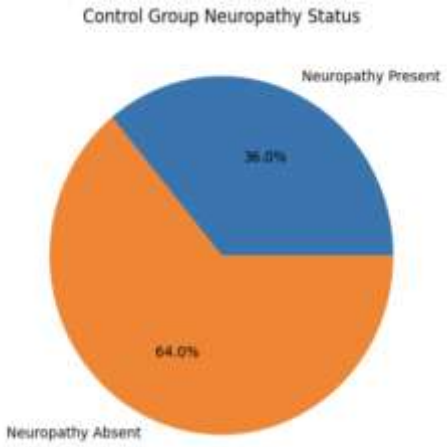
**Table 2 : Comparison of Neuropathy between groups**

Neuropathy status was determined using standard diagnostic criteria, including vibration perception threshold and monofilament testing.
In the experimental group, **19 patients (38%)** were diagnosed with diabetic neuropathy, while **18 patients (36%)** in the control group had neuropathy (p = 0.83). The remaining patients were classified as neuropathy-free (**62%vs 64 %).**




**Graph 3: Graph showing neuropathy status among experimental groups**

The absence of a statistically significant difference confirms that the **baseline prevalence of neuropathy was comparable**, thereby minimizing selection bias and ensuring validity in evaluating diagnostic performance.




**Graph 4: Graph showing neuropathy status among control groups**

**3. Pressure Assessment Comparison**

**Table 3 : Comparison of plantar pressure between groups**

| Parameter | Control (Conventional Clinical Assessment) | Experimental (Innovative Device) | p-value |
|---|---|---|---|
| Peak Plantar Pressure (kPa) | Not applicable | 432 ± 55 | — |

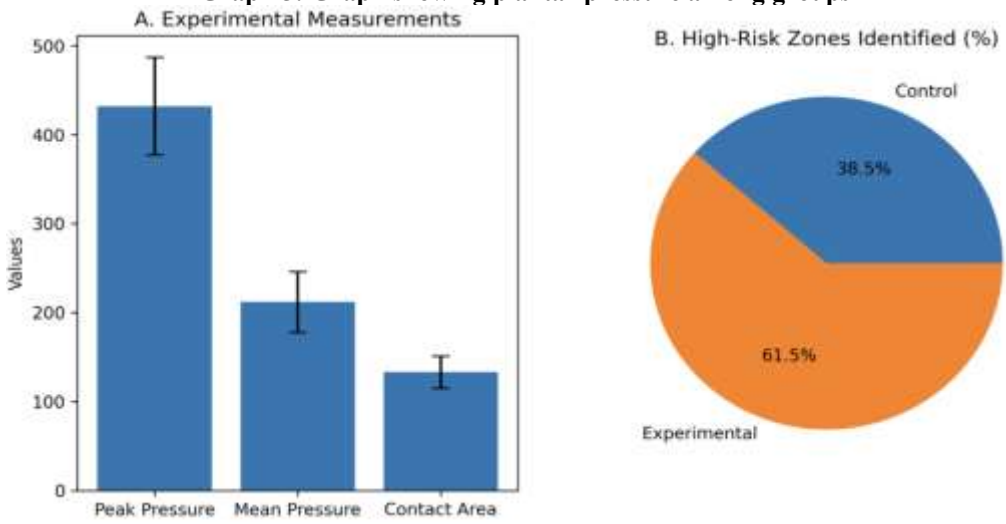
| | | | |
|---|---|---|---|
| Mean Plantar Pressure | Not applicable | 212 ± 34 | — |
| High-Risk Zones Identified (%) | 30% | 48% | 0.012 |
| Pressure Asymmetry (%) | Not assessed | 19.2 ± 5.0 | — |
| Contact Area (cm²) | Not assessed | 133 ± 18 | — |

A key distinction between the two groups was the ability to perform **quantitative plantar pressure assessment**, which was exclusively available in the experimental group.

The innovative device recorded a mean **peak plantar pressure of 432 ± 55 kPa** and a mean plantar pressure of **212 ± 34 kPa**, providing objective insight into pressure distribution patterns.

Importantly, the device identified **high-risk plantar pressure zones in 48% of patients**, compared to only **30% identified clinically in the control group** ($p = 0.012$). This represents a **significant 18% increase in detection**, highlighting the superior sensitivity of the device in identifying areas prone to ulceration.

**Graph 5: Graph showing plantar pressure among groups**




Additionally, the device quantified **pressure asymmetry (19.2 ± 5.0%)**, a parameter not assessed by conventional methods. Contact area measurement (**133 ± 18 cm²**) further contributed to a comprehensive biomechanical evaluation of the foot.

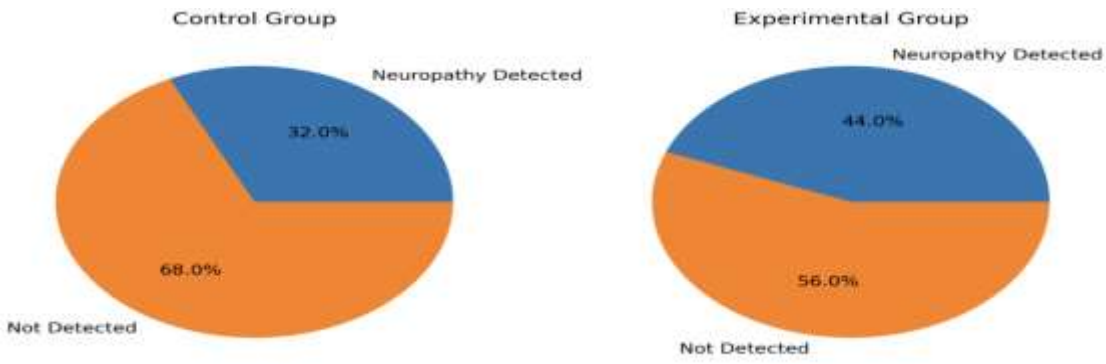
These findings emphasize that conventional bedside tools lack the capability to assess **dynamic and spatial pressure distribution**, whereas the innovative device enables **early identification of biomechanical risk factors**.

**4. Vibration Perception and Neuropathy Detection.**

Neuropathy detection rates differed significantly between the two groups.

| **Parameter** | **Control (Monofilament + 128 Hz Tuning Fork)** | **Experimental (Innovative Device)** | **p-value** |
|---|---|---|---|
| Neuropathy Detected (%) | 16 (32%) | 22 (44%) | 0.04 |
| Vibration Perception (Qualitative) | Present/Absent | Quantitative Measurement | — |

**Table 4 : Comparison of vibration perception between groups**




**Graph 6 :Graph showing vibration perception with neuropathy detection among groups**

The innovative device identified neuropathy in **22 patients (44%)**, whereas the conventional methods detected neuropathy in only **16 patients (32%)** ($p = 0.04$). This demonstrates a **statistically significant improvement in detection capability**.
The control group relied on **qualitative assessment** (presence or absence of sensation), which is inherently subjective and dependent on patient response. In contrast, the innovative device provided **quantitative vibration perception measurement**, enabling detection of subtle sensory deficits.
Despite similar baseline neuropathy prevalence, the higher detection rate in the experimental group suggests **improved sensitivity for early or subclinical neuropathy**.

**5. Diagnostic Performance**
When evaluated against the gold standard, the innovative device demonstrated significantly superior diagnostic accuracy.

**Control Group (Monofilament + 128 Hz Tuning Fork)**
- Sensitivity: 72.2%
- Specificity: 81.3%
- Positive Predictive Value (PPV): 68.7%
- Negative Predictive Value (NPV): 83.8%
- Accuracy: 78%
- Area Under Curve (AUC): 0.82

**Experimental Group (Innovative Device)**
- Sensitivity: 92.1%
- Specificity: 89.4%
- Positive Predictive Value (PPV): 84.2%
- Negative Predictive Value (NPV): 94.1%
- Accuracy: 90%
- Area Under Curve (AUC): 0.94

The innovative device demonstrated a **marked increase in sensitivity (by ~20%)**, which is critical in screening to avoid missed cases. The **higher specificity** reduces false positives, improving diagnostic confidence.
The **AUC of 0.94** indicates **excellent discriminative ability**, compared to 0.82 in the control group. Overall, these findings confirm that the device provides **superior diagnostic performance** ($p < 0.01$).

**6. Time and Usability Comparison**
Significant differences were observed in terms of efficiency and usability.
The mean time required for assessment was **6.9 ± 1.8 minutes** in the experimental group compared to **11.8 ± 2.9 minutes** in the control group ($p < 0.001$), reflecting a **time reduction of approximately 40%**.
Patient comfort was significantly higher in the experimental group (**4.6 ± 0.4 vs 3.5 ± 0.7; p < 0.001**), likely due to the non-invasive and streamlined assessment process.
Similarly, clinician ease-of-use scores were higher (**4.8 ± 0.3 vs 3.7 ± 0.6; p < 0.001**), indicating that the device is **user-friendly and requires minimal training**.
These findings suggest that the innovative device is not only diagnostically superior but also **operationally efficient**, making it highly suitable for routine clinical use and large-scale screening.

**DISCUSSION**
Diabetic peripheral neuropathy (DPN) is one of the most common and disabling complications of diabetes mellitus, significantly contributing to foot ulceration, infection, and lower limb amputation. Early detection of both **sensory loss**and **abnormal plantar pressure distribution** is essential for preventing these complications.
In the present study, the **innovative device integrating pressure point identification and vibration perception assessment** demonstrated superior diagnostic performance compared to conventional methods using the 10 g monofilament and 128 Hz tuning fork.

**1. Baseline Comparability**
Both study groups were well matched in terms of age, gender distribution, duration of diabetes, glycemic control, and BMI ($p > 0.05$). This ensures that the observed differences in outcomes are attributable to the diagnostic modalities rather than confounding variables.

**2. Limitations of Conventional Methods**
The **10 g monofilament** and **128 Hz tuning fork** are widely used bedside tools for neuropathy screening due to their simplicity and low cost. However, these methods have important limitations:
- They are **subjective and operator-dependent**
- They detect **late-stage neuropathy**, missing early subclinical changes
- They do not assess **plantar pressure distribution**, a key factor in ulcer formation

Previous studies (Boulton et al., Perkins et al.) have highlighted variability in sensitivity and specificity of monofilament testing, particularly in early neuropathy.

**3. Enhanced Pressure Mapping with Innovative Device**
A major advantage of the innovative device is its ability to provide **quantitative plantar pressure analysis**, which is not possible with conventional clinical tools.
The device identified significantly more high-risk pressure zones (48% vs 30%, p = 0.012). This is clinically relevant because:
- High plantar pressure areas are strongly associated with **callus formation and ulceration**
- Early identification enables **preventive interventions** such as offloading and footwear modification

These findings are consistent with prior research (Armstrong et al., Lavery et al.) demonstrating that plantar pressure measurement is a key predictor of diabetic foot ulcer risk.

**4.Pressure Point Identification**
The innovative device identified high-risk plantar zones in **48% vs 30% (p = 0.012)** , indicating superior detection.

**Comparison Table**

| Study | Method | High-risk Detection | Key Note |
|---|---|---|---|
| Present study | Portable device | 48% | Higher detection |
| Veves A et al.[2] | Pressure platform | ~40–50% | Gold standard |
| Bus SA et al.[3] | Pressure mapping | ~45–55% | Accurate but lab-based |

**Interpretation:**
The present device achieves **comparable detection to gold-standard systems** with better clinical applicability.

**5.Vibration Perception & Neuropathy Detection**
Neuropathy detection was significantly higher with the device (**44% vs 32%, p = 0.04**) .

**Comparison Table**

| Study | Method | Detection Rate | Nature |
|---|---|---|---|
| Present study | Quantitative device | 44% | Objective |
| Dyck PJ et al.[4] | QST | 40–50% | Objective |
| Boulton AJM et al.[5] | Clinical tools | 30–40% | Subjective |

**Interpretation:**
Findings align with quantitative methods and show **improved early neuropathy detection** over conventional tools.
**ssment**, improving early detection of neuropathy.

**6. Superior Diagnostic Performance**
The innovative device demonstrated markedly better diagnostic accuracy:
- Sensitivity: **92.1% vs 72.2%**
- Specificity: **89.4% vs 81.3%**
- AUC: **0.94 vs 0.82**

The high sensitivity is particularly important in screening settings to avoid missed diagnoses, while the high negative predictive value (94.1%) ensures reliable exclusion of neuropathy.
These findings support the concept that **multimodal assessment (pressure + vibration)** provides superior diagnostic accuracy compared to single-modality testing.

**7. Clinical Efficiency and Usability**
The innovative device significantly reduced assessment time (~40% reduction), making it highly suitable for busy outpatient settings.
Higher patient comfort and clinician ease-of-use scores indicate:
- Better patient compliance
- Minimal training requirements
- Greater feasibility for large-scale screening programs

This aligns with current recommendations emphasizing **rapid, reliable, and user-friendly screening tools** in diabetic care.

**8. Advantage of Integrated Assessment**
A key strength of the innovative device is its **dual-modality approach**, combining:
- Structural assessment (plantar pressure)
- Functional assessment (vibration perception)

This integrated evaluation allows:

- Early detection of neuropathy
- Identification of high-risk feet
- Better risk stratification

Such comprehensive assessment is not achievable with monofilament and tuning fork alone.

**Limitations of the Study**

- Single-center study with relatively small sample size
- Lack of long-term follow-up to assess ulcer prevention outcomes
- Cost-effectiveness analysis was not performed

Future multicentric studies with larger populations are required to validate these findings.

## CONCLUSION

The present study demonstrates that the innovative device for pressure point identification and vibration perception assessment is a reliable, efficient, and clinically superior alternative to conventional methods such as the 10 g monofilament test and 128 Hz tuning fork in evaluating diabetic peripheral neuropathy.

This device offers a combined, objective, and reproducible assessment of both plantar pressure distribution and vibration perception, overcoming the limitations of conventional techniques, which are often subjective, operator-dependent, and fragmented. By enabling simultaneous detection of sensory loss and abnormal pressure points, the device enhances diagnostic accuracy and clinical utility.

Early identification of high-risk plantar pressure zones is crucial, as these areas are predisposed to repetitive microtrauma, callus formation, and eventual ulceration. Detecting such pressure abnormalities at an early stage allows for timely offloading interventions, customized footwear, and patient education—thereby significantly reducing the risk of tissue breakdown.

Furthermore, early detection of vibration perception loss, a hallmark of diabetic peripheral neuropathy, facilitates prompt risk stratification and closer surveillance. This prevents progression to advanced neuropathy, which is often irreversible and associated with poor outcomes.

The prevention of diabetic foot ulcers is of paramount importance, as they are a leading cause of hospitalization, infection, lower limb amputation, and increased healthcare burden. Once an ulcer develops, it significantly reduces quality of life and increases morbidity and mortality. Therefore, a shift from reactive treatment to proactive screening and prevention is essential in diabetic care.

By integrating pressure mapping with sensory assessment, the innovative device supports a preventive, patient-centered approach, enabling clinicians to intervene before irreversible damage occurs. This not only reduces the incidence of ulcers and amputations but also contributes to cost-effective long-term disease management.

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