References: Independent peer-reviewed publications focusing on peripheral neuropathy in diabetes

Updated March, 2024

New Original Research Evaluating the Use of Monofilament in Diabetes

1. Dunker et al. Diagnostic accuracy of the 5.07 monofilament test for diabetes polyneuropathy: influence of age, sex, neuropathic pain and neuropathy severity. *BMJ Open Diabetes Research and Care.* 2023. Pubmed Link

   *"This multicenter study demonstrates poor diagnostic performance for the 5.07/10 g SWME [monofilament] in patients with diabetes referred to polyneuropathy assessments…**The monofilament test should not be used to diagnose DPN, nor be used as an inclusion tool in diabetes research**."*

   - Study investigates the diagnostic performance of the monofilament test

Original Research Using DPNCheck

1. Hayashi et al. Simplified electrophysiological approach combining a point-of-care nerve conduction device and an electrocardiogram produces an accurate diagnosis of diabetic polyneuropathy. *Journal of Diabetes Investigation.* 2024. Pubmed Link

   "We have developed an estimation formula with excellent diagnostic performance. The use of DPNCheck and electrocardiogram would simplify the diagnosis of diabetic polyneuropathy, making it more accessible, reproducible and reliable."

   - Study investigates the diagnostic performance of DPNCheck

2. Goonoo, et al. 489-P: Abnormal Combined Point-of-Care-Device DPN-Check and SUDOSCAN Results Predict All-Cause Mortality in People with Diabetes. Diabetes 2023 Link to Article

   *"Abnormal combined DPN-Check and SUDOSCAN results predict all-cause mortality after adjusting for other risk factors. However, **10g-MFT [monofilament] and TCNS that diagnose DPN late did not predict all-cause mortality**."*

   - Study investigates the diagnostic performance of DPNCheck

3. Fukuda et al. Association between Diabetic Peripheral Neuropathy as Measured Using a Point-of-Care Sural Nerve Conduction Device and Urinary Albumin Excretion in Patients with Type 2 Diabetes. *Journal of Clinical Medicine.* 2023. Pubmed Link

   "Patients with DPN-Check-determined diabetic peripheral neuropathy had significantly higher urinary albumin excretion than those without, while there was no difference in urinary albumin excretion between patients with and without diabetic peripheral neuropathy determined by simplified diagnostic criteria"

   - Study investigates the diagnostic performance of DPNCheck
   - Study evaluates the ability of DPNCheck to accurately predict or detect microvascular complications

4. Ke et al. A Nomogram for Predicting Vision-Threatening Diabetic Retinopathy Among Mild Diabetic Retinopathy Patients: A Case–Control and Prospective Study of Type 2 Diabetes. *Diabetes, Metabolic Syndrome and Obesity.* 2023. Pubmed Link

   "We combined Amp and CV and graded severity of SNCI, and the new finding indicated SNCI [as determined by DPNCheck] could be a strong predictor of VTDR [vision-threatening diabetic retinopathy]… SNCI, UACR, and 2-h C-peptide are more effective predictors of progression than HbA1c and duration of diabetes."

   - Study investigates the diagnostic performance of DPNCheck
   - Study evaluates the ability of DPNCheck to accurately predict or detect microvascular complications

5. Nattero-Chávez et al. Point-of-care sural nerve conduction could predict the presence of. cardiovascular autonomic neuropathy in type 1 diabetes mellitus. Journal of Diabetes Investigation. 2022. Pubmed link

   "In summary, our findings indicate that a combination of POCD [point of care device] recordings and few clinical variables is accurate enough to effectively rule out asymptomatic CAN [cardiac autonomic neuropathy] in patients with T1D at the clinical setting."

   - Study investigates the diagnostic performance of DPNCheck
   - Study evaluates the ability of DPNCheck to accurately predict or detect microvascular complications

6. Kamiya et al. A point-of-care nerve conduction device predicts the severity of diabetic polyneuropathy: a quantitative but easy-to-use prediction model. Journal of Diabetes Investigation. 2021. Pubmed link

   "Nerve conduction parameters in the sural nerve acquired by the handheld device successfully predict the severity of DPN."

   - Study investigates the diagnostic performance of DPNCheck

7. Sheshah et al. Integrating microvascular assessments into one clinic, in an annual one-stop approach. Journal Diabetes Metab Disord Control. 2020. Link to article

   "The prevalence of diabetic peripheral neuropathy (DNP) according to the neuropathy disability score, which is our gold standard test was 13.8% and using 10-g monofilament test was 19.5%. Meanwhile, the prevalence of DNP according to DPN-check was 40.9% …"

   - Study investigates the diagnostic performance of DPNCheck

8. Pafili et al. Clinical Tools for Peripheral Neuropathy to Exclude Cardiovascular Autonomic Neuropathy in Type 2 Diabetes Mellitus. Diabetes Therapy. 2020. Pubmed link

   "Abnormality in sural nerve conduction parameters as evaluated with the use of NC-stat®/DPNCheck™ device was associated with a threefold higher likelihood of CAN …"

   - Study investigates the diagnostic performance of DPNCheck
   - Study evaluates the ability of DPNCheck to accurately predict or detect microvascular complications

9. Shibata et al. Validity and reliability of a point-of-care nerve conduction device in diabetes patients. Journal of Diabetes Investigation. 2019. Pubmed link

   "The point-of-care device has excellent reproducibility and good agreement with standard. electromyography system. The device might be useful to evaluate diabetic polyneuropathy."

- Study investigates the diagnostic performance of DPNCheck

10. Papanas et al. Automated measurement of sural nerve conduction is a useful screening tool for peripheral neuropathy in type 1 diabetes mellitus. Rev Diabet Stud. 2019. Pubmed link

   "In conclusion, the findings of this study suggest that the NC-stat® DPNCheck™ device yields high sensitivity and specificity for the diagnosis of DPN in T1DM [type 1 diabetes mellitus]."

   - Study investigates the diagnostic performance of DPNCheck

11. Binns-hall et al. One-stop microvascular screening service: An effective model for the early detection of diabetic peripheral neuropathy and the high-risk foot. Diabetic Medicine. 2018. Pubmed link

   *"The prevalence of distal symmetrical polyneuropathy, assessed using the Toronto Clinical Neuropathy Score, was **30.9**%, and was underestimated by 10-g monofilament test (**14.4%**). The prevalence of distal symmetrical polyneuropathy using DPNCheck was **51.5%** (84.3% sensitivity, 68.3% specificity) ..."*

   - Study investigates the diagnostic performance of DPNCheck

12. Scarr et al. Validity of a point-of-care nerve conduction device for polyneuropathy identification in older adults with diabetes: Results from the Canadian Study of Longevity in Type 1 Diabetes. Plos One. 2018. Pubmed link

   "The POCD [point of care device] has strong agreement and diagnostic accuracy for identification of polyneuropathy in a high-risk subgroup and thus may represent a sufficiently accurate and rapid test for routinely detecting those with electrophysiological dysfunction."

   - Study investigates the diagnostic performance of DPNCheck

13. Kural et al. The Utility of a Point-Of-Care Sural Nerve Conduction Device for Detection of Diabetic Polyneuropathy: A Cross-Sectional Study. Muscle & Nerve. 2018. Pubmed link

   "The POCD [point of care device] may be used as a suitable screening tool for detection of DPN."

   - Study investigates the diagnostic performance of DPNCheck

14. Chatzikosma et al. Evaluation of Sural Nerve Automated Nerve Conduction Study in the Diagnosis of Peripheral Neuropathy in Patients with Type 2 Diabetes Mellitus. Archives of *Medical Science.* 2016. Pubmed link

   "Sural nerve automated NCS with the NC-stat DPNCheck device exhibits high sensitivity and specificity for the diagnosis of DPN in T2DM [type 2 diabetes mellitus]."

   - Study investigates the diagnostic performance of DPNCheck

15. Sharma et al. Assessment of Diabetic Neuropathy Using a Point-of-Care Nerve Conduction Device Shows Significant Associations With the LDIFLARE Method and Clinical Neuropathy Scoring. Journal of Diabetes Science and Technology. 2015. Pubmed link

   "Thus, the NC-stat|DPNCheck™ system appears to be an excellent adjunctive diagnostic tool for diagnosing DPN in the clinical setting."

   - Study investigates the diagnostic performance of DPNCheck

16. Lee et al. Reliability and Validity of a Point-of-Care Sural Nerve Conduction Device for Identification of Diabetic Neuropathy. *Plos One.* Jan 2014. Pubmed link

    "The POCD [point of care device] demonstrated excellent reliability and acceptable accuracy."

    - Study investigates the diagnostic performance of DPNCheck

17. Perkins et al. Validation of a novel point-of-care nerve conduction device for the detection of diabetic sensorimotor polyneuropathy. *Diabetes Care*. 2006. Pubmed link

    "A novel point-of-care device has excellent diagnostic accuracy for detecting electrophysiological abnormality in the sural nerve of patients who have diabetes. This automated device represents an alternative to conventional nerve conduction studies for the diagnosis of diabetic sensorimotor polyneuropathy."

    - Study investigates the diagnostic performance of DPNCheck

Review Articles about DPNCheck

1. Lew et al. Diabetes Distal Peripheral Neuropathy: Subtypes and diagnostic and screening technologies. *Journal of Diabetes Investigation*. 2022. Pubmed link

    "Yet, DPNCheck, approved by the Food and Drug Administration (FDA), is sufficiently accurate and reliable for use as a screening technology."

2. Carmichael et al. Advances in Screening, Early Diagnosis and Accurate Staging of Diabetic Neuropathy. *Frontiers in Endocrinology*. 2021. Pubmed link

    "It [DPNCheck] has been validated in type 1 and 2 diabetes populations through comparison with the Neuropathy Disability Score (NDS) (55) and standard NCS (53, 54). These studies have reported a high sensitivity of 92-95% for detecting abnormalities."

3. Himeno et al. Lumos for the long trail: Strategies for clinical diagnosis and severity staging for diabetic polyneuropathy and future directions. *Journal of Diabetes Investigation*. 2020. Pubmed link

    "This device [DPNCheck] will provide accessible, objective and repetitive assessment of DPN even in developing areas with limited medical resources."

4. Selvarajah et al. Diabetic peripheral neuropathy: advances in diagnosis and strategies for screening and early intervention. *The Lancet Diabetes & Endocrinology*. 2019. Pubmed link

    "DPNCheck has been shown to have very good reliability (inter-observer 0.83 and intraobserver 0.97 intraclass correlation coefficients) for sural nerve action potentials. It also has good validity, with 95% sensitivity and 71% specificity when compared against a reference standard nerve conduction study for the diagnosis of DPN."

5. Pafili et al. NC-stat (DPNCheck) for the Diagnosis of Diabetic Polyneuropathy. *Expert Review of Medical Devices*. 2017. Pubmed Link

    "… it is the authors' recommendation that NC-stat®/DPNCheck™ could play an important role, especially in the primary care setting, as a screening tool for DPN although clearly, more clinical experience is highly welcome."