# Reproducibility of a rapid point-of-care sural nerve conduction test

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## OBJECTIVE

The objective of this study was to quantify the reproducibility of point-of care (POC) sural nerve conduction.

## BACKGROUND

Nerve conduction studies (NCS) are the most accurate and reproducible test for diabetic peripheral neuropathy (DPN). They are used in clinical settings and as an outcome measure in neurotherapeutic clinical trials. However, NCS have not been widely adopted in the clinical management of diabetes due to expense, limited availability, and complexity. A 1-minute, low cost, sural nerve conduction test, NC-stat® DPNCheck™, is now available as a POC biomarker of DPN. In order to be clinically useful, this test must have high reproducibility so small changes in nerve function are reliably identified.

## METHODS AND MATERIALS

Seventeen subjects (15 male, age 27-64) without peripheral neuropathy were evaluated in two sessions 7-14 days apart. In each session, sural conduction velocity (CV) and amplitude (Amp) were measured twice in each leg. The device was removed and repositioned with every test.

**Table 1.**

| Subjects | |
|---|---|
| Total subjects | 17 (15M/2F) |
| Age | 27 - 64 |
| Total tests | 136 |
| Mean CV | 55.8 ± 3.5 m/s |
| Mean Amp | 14.3 ± 4.2 mV |

CV - Conduction Velocity (onset)
Amp - Amplitude (peak to peak)

The device corrects CV for skin temperature below 30°C. The primary outcome measure was variance component analysis and the corresponding coefficient of variation (CoV).

**Table 2.**

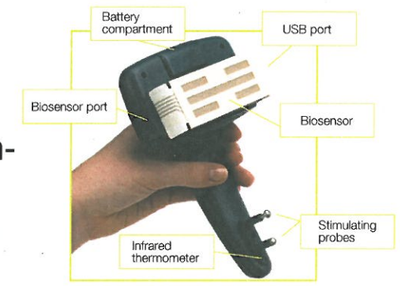
| Evaluation | CV | Amp | Log (Amp) |
|---|---|---|---|
| Between-session CoV | 3.6% | 8.8% | |
| Within-session CoV | 2.4% | 8.2% | |
| Session-test CoV | 4.3% | 12.0% | 5.4% |
| Session-test CoV* | 3.4% | 8.5% | 3.8% |

CoV - coefficient of variation
Session-test CoV* - average of left and right limbs

## RESULTS

A total of 136 tests were conducted. CV was 55.8±3.5 m/s and Amp was 14.3±4.2 μV. Between-session CoV was 3.6% and 8.8% for CV and Amp, respectively. Within-session CoV was 2.4% (CV) and 8.2% (Amp). The session-test CoV, which quantifies the total variation between sessions, was 4.3% (CV) and 12.0% (Amp). Log-transforming the Amp reduced its CoV to 5.4%. Averaging the left and right limbs reduced the session-test CoV to 3.4% (CV), 8.5% (Amp), and 3.8% (log(Amp)).

## CONCLUSION




A 1-minute POC sural nerve conduction test demonstrated high reproducibility in a non-neuropathic cohort. Reproducibility can be improved by log transforming the amplitude and combining bilateral data. These results are comparable to benchmark studies in which measurements were performed manually in controlled multi-center clinical trials.