

Horizon Scan Report 0020

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## Diagnostic Technology: Hand-held nerve conduction measurement devices for carpal tunnel syndrome

### Clinical Question:

In patients with suspected carpal tunnel syndrome (CTS), what is the accuracy and utility of a hand-held nerve conduction testing device in diagnosis and management over existing methods of diagnosis and severity assessment?

### Background and Importance:

Symptomatic carpal tunnel syndrome is common with an estimated prevalence between 0.5 to 3% [1], and is associated with certain risk factors including female gender, pregnancy, hypothyroidism and diabetes [1-3]. Typical symptoms include intermittent paraesthesia of the fingers, and forearm pain [1,2], and are a common cause for patients to seek consultation with a medical practitioner. Symptoms can resolve or significantly improve without treatment [2]. Conservative treatment with splints and local steroid injections can be effective; however, in up to 80% of cases symptoms will recur within a year [4]. In severe or non-responding cases, or in cases of diagnostic doubt [3,5,6], nerve conduction studies can be performed to confirm a documented neurophysiological diagnosis of carpal tunnel syndrome, and before considering surgical decompression [6].

However, there is debate about what is the diagnostic gold standard for carpal tunnel syndrome [7-10], and amongst clinicians about the appropriate use of electrophysiological techniques. Many clinicians suggest limited clinical benefit from conventional nerve conduction studies in patients with high clinical suspicion and high pre-test probability for carpal tunnel syndrome [2,9,10]. Nerve conduction studies can also identify alternative neurological diagnoses such as cervical radiculopathies, polyneuropathies or musculoskeletal disorders [11], and assess the severity of disruption of median nerve conduction in cases of confirmed neurophysiological carpal tunnel syndrome. In such cases, nerve conduction studies can provide an objective measure to guide diagnostic decisions and prior to surgery can provide objective evidence of the operative indication [6]. Some critics have questioned the relationship between abnormal neurophysiological findings from nerve conduction studies and patient symptoms, with cases of patients with normal nerve conduction finding significant relief from carpal tunnel decompression. Simple clinical provocation tests such as Phalen's sign, Tinnel's sign, and Katz hand diagrams have shown variable diagnostic accuracy [1].

### Advantages over Existing Technology:

Conventional nerve conduction studies are performed by trained neurophysiologists with access to specialist equipment, are time-consuming, both in testing and interpretation, and can be uncomfortable for the patient, particularly if needle electromyography (EMG) is used [12]. Availability of testing is dependent on appropriate facilities and local waiting times. Hand-held devices could offer several potential advantages to conventional nerve conduction studies if they are diagnostically robust: testing is quick and easy to perform; can be performed by any trained professional; offers immediate access, and is relatively painless for the patient [2,13]. Accuracy of such devices in primary care has yet to be evaluated, although there have been concerns about over-diagnosis from use in other settings [14]. Additional concerns include the limited ability of point-of-care testing to detect alternative diagnoses [2].

### Details of Technology:

They are battery powered portable devices, and usually take up to 20 minutes to perform the nerve conduction testing. They rely on operator-placed skin pads on the patient's digit(s) and forearm to collect the nerve conduction data. The nerve conduction data is collected within the hand-held device, and is often then downloaded to a computer. The device frequently relies on data transmission to an external source to provide a report for the operator. The devices are marketed as being easy to use in the clinic setting. See Table 1 for further details of the devices.

**Table 1. Point-of-care testing devices for carpal tunnel syndrome**

Device (manufacturer)	Latencies* and nerves tested	Assessment time	Pad placement and details of operator instructions	Analysis and reporting details	External agency regulation
<b>NC-stat</b> (NeuroMetrix, Inc., USA) [12,16-18]	Motor and sensory latencies; Median and ulnar nerves	2-20 minutes (each hand)	<ul style="list-style-type: none"> <li>Wrist and digit-specific median (3<sup>rd</sup> digit) and median plus ulnar nerve electrode pads.</li> <li>Automated operator instructions: electrode placement, skin surface temperature correction, determination of nerve stimulation intensity, analysis of evoked neuroelectrical responses</li> <li>Automatically maps stimulus response curve- automatically advises retest if acceptable waveforms not obtained</li> </ul>	Simple handheld user interface- data stored and downloadable to computer. Data relayed telephonically to database and report emailed or faxed within minutes. Requires physician to review results in light of clinical findings	FDA clearance CE marked
<b>Mediracer</b> (EMG Technologies, Oulu, Finland) [15,19-21]	Sensory latencies; Median and ulnar nerves	15 minutes (both hands)	<ul style="list-style-type: none"> <li>Wrist and digit-specific median (2<sup>nd</sup> digit) and median plus ulnar (4<sup>th</sup> digit) nerve electrode</li> <li>Automated battery check and noise level determination; sensory threshold defined and stimulus intensity adjusted; total 64 stimuli delivered and averaged; signals rejected if above noise threshold</li> </ul>	Automatic algorithm detects peaks- peaks displayed on device screen. - Data transferred to PC via infrared link- results encrypted and sent to database for interpretation by consultant. Report accessible by logging onto secured website	CE marked
<b>NervePace or Brevio</b> (NeuMed/Neurotron Medical, USA) [13]	Motor latencies	ns**	<ul style="list-style-type: none"> <li>Stimulator intensity gradually increased until muscle contraction observed</li> </ul>	Device screen displays time delay between stimulus and motor response. Printout of numerical latency value given	FDA clearance (CE mark unknown)
<b>Neurosentinel</b> (HealthSouth O.P.D., Inc., USA) [13]	Sensory latencies; Median nerve	ns	<ul style="list-style-type: none"> <li>Paediatric electrocardiogram electrodes fixed to distal forearm, and recordings taken from 3<sup>rd</sup> digit</li> </ul>	Response curves recorded- only after 4 stimuli produce results with <10% variation	unknown
<b>Axon II</b> , (PainDx, USA) [22]	Sensory latencies	15 minutes	ns (note: point of care device, but not handheld)	ns	FDA clearance CE marked
<b>Advance NCS</b> (NeuroMetrix Inc., USA) [23]	Motor and sensory latencies; Median and ulnar nerves	10 minutes	<ul style="list-style-type: none"> <li>Wrist and digit electrodes</li> <li>Touch screen system</li> </ul>	Detailed results report- comparison to normal limits, waveforms, longitudinal tracking, reference statements	FDA clearance CE marked
<b>Neurometer®</b> (Neurotron, USA) [24]	Sensory latencies; Median and ulnar nerves	20 minutes per site	<ul style="list-style-type: none"> <li>Digit-specific median (thumb and 2<sup>nd</sup> digit) and ulnar (5<sup>th</sup> digit) nerve electrodes</li> <li>Automated operator instructions- pre-examination cable test</li> <li>Auto test begins- adjustment of output intensity- automated testing sequence- repeated for 3 stimulation frequencies</li> </ul>	Neurologist with appropriate training interprets results using graded data analysis, other lab data, and clinical picture- data analysis summary sheet provided	FDA clearance (CE mark unknown)

\*latency = time for nerve stimulus to be sensed by recording electrode (both at specific sites) [30].

\*\*ns = not specified

### Patient Group and Use:

- Hand-held device manufacturers recommend use in patients with symptoms suggestive of carpal tunnel syndrome [15].

### Previous Research:

#### *Accuracy compared to existing technology*

Though several studies have been undertaken, only a few have compared the accuracy of hand-held devices with conventional nerve conduction studies. We identified published studies for four of the devices: NC-stat [16,25], Nervepace (Brevio) [13,26], Neurosentinel [13] and Mediracer [20]. No published accuracy studies were identified for the other devices.

Of the identified literature, five studies compared the hand-held device with nerve conduction studies, all in high-prevalence settings i.e. secondary care nerve conduction laboratories [16,20,25], a regional carpal tunnel service [19] and presumed orthopaedic setting [26]. In other studies there was no 'gold-standard' comparison group [12,17,21]. Others focussed on assessing the effect of using a hand-held device on clinical waiting times and cost, without an assessment of diagnostic accuracy [18,21].

#### NC-Stat [16,25]

An accuracy study of NC-stat found that there was good agreement between NC-stat and traditional nerve conduction studies in 33 adults referred for nerve conduction testing that included the median and ulnar nerves at the wrist (sensitivity 94-100% and specificity 85-94%). However they found that specificity was compromised at the manufacturer's suggested diagnostic thresholds, so instead modified the thresholds they used. The patient population studied also had a high pre-test probability of carpal tunnel syndrome, since all subjects were recruited from patients referred for nerve conduction studies, including of the median and ulnar nerves at the wrist [25]. Another study reported a sensitivity of distal motor latency (DML) measurement by NC-stat compared to a standardised definition of carpal tunnel syndrome (which included clinical data and conventional nerve conduction studies) to be 87% in 75 patients referred for upper limb nerve conduction studies [16].

#### Nervepace [13,26]

A case control study of 60 patients with diagnosed carpal tunnel syndrome and 15 healthy volunteers found that the reliability and accuracy of the Nervepace testing device compared to conventional nerve conduction studies was unacceptable at DMLs >6.0ms, which is just 2.0ms greater than the upper limit of normal nerve conduction used in this study (below this, the two methods correlated well). In addition DML was unmeasurable in 14 hands by Nervepace, and these were excluded from the final analysis [26].

#### Neurosentinel [13]

A literature review deemed Neurosentinel and Nervepace not to be effective substitutes for nerve conduction studies in patients with suspected carpal tunnel syndrome [13].

#### Mediracer [19,20]

A study of 194 patients with clinically suspected carpal tunnel syndrome who had been referred for nerve conduction studies, and 95 healthy volunteers, found that the automated Mediracer program had a sensitivity of 80.8% and specificity of 92.1% compared to conventional nerve conduction studies. However, 9% of Mediracer measurements failed, and digital data was lost for 15 patients when transferred from study unit to main server [20]. Agreement between Mediracer and Keypoint portable devices in 65 patients referred to secondary care with suspected carpal tunnel syndrome was 94% [19].

#### *Impact compared to existing technology*

A UK study compared 71 patients with suspected CTS who attended a hand clinic, with 71 age-matched controls from the same clinic who underwent traditional NCS. It found that NC-stat reduced waiting time to surgery and cost per patient [18]. A similar study looked at 141 patients referred from orthopaedic outpatients at a district general hospital, and found that use of the Mediracer device reduced waiting time for both nerve conduction testing and surgery by removing the need for external NCS testing after the initial orthopaedic appointment, with subsequent orthopaedic follow-up before listing for surgery, as well as reducing cost [21].

As well as availability and cost, conventional NCS can be associated with considerable patient discomfort, which is removed by hand-held devices. Another advantage is that such devices do not require specialist expertise, other than training of a health provider in the specific use of that device [18].

#### *Guidelines and Recommendations*

Use of hand-held device testing of median nerve conduction in suspected CTS is not recommended by the British Society for Surgery to the Hand (BSSH) or the American Academy of Orthopedic Surgeons [5,6]. BSSH guidance for use of conventional NCS is when the diagnosis is equivocal, and is not therefore required routinely [5]. Hand-held devices are also not mentioned in the NHS Clinical Knowledge Summary, which recommends referral for EMG and nerve conduction studies if the diagnosis is uncertain [3]. The UK Department of Health published a Good Practice Guide in 2007 entitled “Transforming Clinical Neurophysiology Diagnostic Services to Deliver 18 Weeks”. In this guide, hand-held tests for use in CTS specifically are discussed, with advice given that such devices are limited in the range of measurements possible, and that their absolute accuracy and clinical utility is still being evaluated. The guide suggests that such devices “require further assessment, but should be kept under review given their potential use in primary care” [29].

#### **Cost-effectiveness and economic impact:**

Limited published evidence exists on the cost-effectiveness of hand-held conduction measurement devices for diagnosis CTS. Bourke et al. report on a cost comparison conducted on 71 patients with suspected carpal tunnel syndrome using a handheld, non-invasive electrophysiological device (NC-stat®) compared with a similar cohort of 71 age-matched patients who received formal electrophysiological testing [18]. The use of NC-stat® resulted in a significantly ( $p < 0.0001$ ) reduced time from presentation to surgery, from 198 days to 102 days. Their simple cost comparison resulted in an average per patient cost of £176.90 for those diagnosed using NC-stat® (£3,995 equipment cost, disposable electrodes £29 with average of 2.9 per patient, one additional nurse for a clinic once a fortnight, 20% referral rate to additional electrophysiological testing) compared with an average per patient cost of £210 (trust charge) for formal electrophysiological testing.

#### **Research Questions and suggested next steps:**

1. What is the diagnostic accuracy of hand-held device nerve conduction testing compared with conventional NCS? This needs to be established by means of rigorous diagnostic accuracy studies involving patient populations and settings which include primary care and orthopaedic triage services.
2. What is the role of hand-held device testing in suspected CTS? Guidelines do not recommend testing in cases of high pre-test probability, and the ability of point-of-care tests to detect alternative diagnoses is unclear.
3. There is some evidence that use of a hand-held device in a pre-operative clinic may reduce costs and waiting times for surgery by reducing need for external testing and subsequent follow up appointments. This needs to be verified in larger studies.
4. What is the agreement of accuracy results of the hand-held device among different professionals in primary care?
5. Do the outcomes of patients tested with the hand-held device differ from those tested with the conventional NCS?

#### **Expected outcomes:**

Since there is no clear role for hand-held device testing based on current accuracy data and current guidelines, the potential benefits or harms from implementation are currently unclear. However, if evidence pointed towards a hand-held device as being diagnostically accurate compared to conventional NCS, they could potentially offer significant cost-saving and waiting time reductions.

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**Table 2. Summary of available published evidence surrounding point-of-care carpal tunnel syndrome (CTS) testing devices**

Device	Ref.	Participants	Description of study	Results
NC- Stat	[12]	Retrospective analysis of data registry for NCS performed over 10 consecutive days using NC-stat	1585 limbs with median and ulnar nerve data.	30.5% had normal results, 53.1% indicated CTS and 11% were labelled non-specific neuropathy involving median and ulnar nerves.
	[16]	75 patients referred for upper limb NCS, and 22 asymptomatic volunteers.	NC-stat testing of median nerve. Symptomatic patient underwent traditional NCS, and this was combined with clinical information to give a neurologist's final diagnosis, and a standardised definition.	Distal motor latency had sensitivity 87% for median neuropathy at the wrist based on standardised definition.
	[17]	100 tests from 85 subjects (34 subjects thought to have CTS)	NC-stat used to test all subjects. Nil comparison. Diagnoses before and after testing were compared.	In some cases, the investigator retained pre-test diagnosis despite contradictory NC-stat results. For CTS subjects, reported results were a confirmed diagnosis in 76.5% and an expanded diagnosis in 20.6%. There were no reported cases of a changed diagnosis in CTS subjects.
	[18]	71 patients with suspected CTS presenting to hand clinic in secondary care. 71 age-matched controls who had undergone traditional NCS (also presenting to hand clinic). Suspected complex neurological conditions excluded	NC- stat device used in clinic for group 1. Group 2 referred for traditional NCS testing. Time to decompression surgery and cost analysis calculated for both groups.	12/71 patients referred for NCS testing as NC-stat inconclusive, or suggestive of more proximal lesion. Significantly reduced waiting times for decision and surgery for CTD in the group receiving NC-stat testing compared to traditional NCS testing. Cost saving with NC-stat of £24.48 per patient.
	[27]	Review of available published evidence	9 studies reviewed (Leffler, Rotman, Wells, Vinik, Guyette, Fisher, Elkowitz, Kong, Katz)	Conclusion that there is not adequate evidence that NC-stat is equivalent to traditional NCS for evaluating CTS. Therefore considered experimental and investigational.
NervePace/ Brevio  Neurosentinel	[13]	Literature review	Review of 10 reports	Conclusion that all literature reviewed was flawed in methodology, and often made incorrect electrophysiological assumptions. Therefore Nervepace and Neurosentinel deemed to be experimental and not effective substitutes for NCS in patients with suspected CTS.
	[26]	60 patients with diagnosed idiopathic CTS and 15 healthy volunteers.	Nervepace compared with conventional NCS. Pre- and post-operative measurements were taken.	Unmeasurable hands (17 patients) not included in analysis. Correlation between Nervepace and traditional NCS good below DML 6.0ms, however in DML values >6.0ms the reliability and accuracy of the Nervepace device was unacceptable.
	[28]	Literature review		No evidence addressing diagnostic accuracy of Brevio.
Mediracer	[19]	65 patients referred to secondary care with suspected CTS (92 symptomatic and 34 asymptomatic hands tested).	Mediracer device compared to NCS measurements using Keypoint 4 and Keypoint portable devices	Overall agreement between 2 measuring systems 94%
	[20]	194 patients referred for NCS, with suspected CTS (previous surgery excluded, and those with history or NCS findings of another neurological condition). + 95 health volunteers.	Mediracer device testing for median and ulnar nerves compared with traditional NCS testing, with clinical findings also used in the diagnostic classifications	9% of measurements with Mediracer device failed and the digital data of 15 patients was lost upon transfer to the main server. The automated program showed a sensitivity of 80.8% and a specificity of 92.1% compared to traditional NCS findings.
	[21]	141 patients referred from orthopaedic outpatients	Mediracer device used instead of traditional NCS. No comparison group.	18/141 (12.8%) subjects had to undergo further NCS. Cost saving of >£16k, waiting time for NCS and decompression surgery reduced, fewer outpatient visits.

*NCS, nerve conduction studies*