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2008

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Armstrong, Theodore; Dale, Ann Marie; Al-Lozi, Muhammad T.; Franzblau, Alfred; and Evanoff, Bradley A., "Median and ulnar nerve conduction studies at the wrist: criterion validity of the NC-stat automated device". *Journal of Occupational and Environmental Medicine*, 50, 7, 758-64. 2008.

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Median and Ulnar Nerve Conduction Studies at the Wrist: Criterion Validity of the NC-stat Automated Device

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Prior presentations: PREMUS

Grant & Financial Support:

Funding for this study was provided by CDC/NIOSH grant # R01 OH008017-01. Nerve conduction testing supplies were provided by NEUROMetrix, Inc. Financial support for Theodore Armstrong was provided by the Doris Duke Charitable Foundation.

Financial Disclosure: Aside from the nerve conduction testing supplies provided to the investigators for this study, no party having a direct interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

Running Title: Comparison of NC-Stat to Standard Nerve Conduction Testing**Abstract**

Objective: To obtain results obtained with the NC-stat—an automated nerve testing device—to traditional nerve conduction studies relevant to carpal tunnel syndrome screening.

Methods: Thirty-three subjects recruited from patients referred for electrodiagnostic testing were studied. Measurements including the distal motor latency (DML), distal sensory latency (DSL), and median-ulnar latency difference (MUD) were obtained by the NC-stat and by standard nerve conduction studies.

Results: With modifications to the NC-stat's suggested reference ranges, sensitivity with respect to the traditional results ranged from 93.8% (sensory MUD) to 100% (median DML and DSL) and specificity ranged from 84.6% (motor MUD) to 94.1% (sensory MUD). Sensitivity was as high or higher and specificity was lower using manufacturer's suggested cutoffs.

Conclusions: The NC-stat appears to be a convenient and sensitive method for detecting median nerve pathology at the wrist.

Keywords: nerve conduction studies, electrophysiological testing, carpal tunnel syndrome, post-offer pre-placement testing, neuropathy, screening

Nerve conduction studies (NCS) are a quantitative, objective method for the evaluation of peripheral nerve function. These studies are in routine clinical use and are usually performed by a neurologist or PM&R physician who specializes in electrodiagnosis. The NC-stat (NEUROMetrix Inc, Waltham, MA), a recently developed automated nerve conduction testing device, has been marketed for use by the non-specialist physician. This device could potentially expand the utilization of NCS in settings such as outpatient clinics and epidemiologic field studies because it is portable and requires minimal training to operate correctly. It simplifies the process of electrode placement and automates the technical steps of stimulating nerves and recording the evoked responses. Following testing, the data stored on the device are sent electronically via modem to the manufacturer, where the results are analyzed by a computer and a report is returned to the testing site.

Prior studies have demonstrated that the results of NCS performed with the NC-stat correlate well with those conducted by traditional methods, including motor studies of the median, ulnar, peroneal, and posterior tibial nerves¹⁻⁵ and sensory studies of the median, ulnar and sural nerves.^{6,7} However, a high correlation between two measurements does not guarantee agreement.⁸ In another study, a normal dataset for the median nerve distal motor latency was established in a group of 1,695 asymptomatic industrial workers, but no direct comparison with a reference standard was performed.⁹

The aim of the present study was to use sensitivity, specificity, and statistical measures of agreement to assess the criterion validity of the NC-stat NCS for the median and ulnar nerves at the wrist. NCS performed in an electromyography laboratory at an academic medical center were used as the reference standard. Analogous measurements

of distal latencies were obtained from both methods. Receiver-operator characteristic (ROC) curves were used to assess how well the NC-stat's measurements agreed with the traditionally obtained measurements at classifying subjects as abnormal (sensitivity) or normal (specificity). Correlations were calculated between NCS measurements from the two methods only for comparison to prior studies.

Materials and Methods

Subjects

A volunteer sample of subjects was recruited from patients referred to the electrodiagnostic laboratory in the Center for Advanced Medicine at Washington University Medical Center (St. Louis, MO, USA) between November 12th and December 22nd of 2004. The eligible group of subjects included anyone 18 years of age or older who was referred for electrodiagnostic testing including NCS of the median and ulnar nerves at the wrist. Patients were excluded if they had an internal pacemaker or defibrillator, or if they were pregnant. In an attempt to include a range of neuropathology, patients were not excluded based on the particular diagnosis for which they were referred. At the time eligible patients presented to the electrodiagnostic center, they were given an informational letter of recruitment. A member of the research team met with interested people to obtain written informed consent. Enrolled subjects first received traditional NCS, immediately followed by testing with the NC-stat. This study was approved by the Washington University Medical Center Institutional Review Board.

Traditional NCS

Traditional NCS were performed by a neurologist board certified in electrodiagnostic medicine or by a trained technician under a neurologist's supervision. The examiners who performed and evaluated the traditional tests were blinded to the results of the NC-stat testing. Three different types of equipment were in use in the electrodiagnostic laboratory, so in this study we accepted measurements from all of the following: the Viking Select (Nicolet Biomedical, Madison, WI), the Advantage EMG (Advantage Medical, London, ON, Canada), and the Xcalibur (XLTEK Ltd, Oakville, ON, Canada). Using surface electrodes for stimulus and recording, a variety of conventional measures were obtained for each patient based on the ordering physician's determination of relevance. From these data we extracted the parameters for which the NC-stat made analogous measurements (see below). The traditionally measured parameters compared to those from the NC-stat included the median and ulnar distal motor latency (DML), defined as the time to the initial negative deflection, the distal sensory latency (DSL), defined both by the time to the initial negative deflection and by the time to the negative peak (we used both measures in subsequent comparisons), and the median-ulnar difference (MUD) for the DML and DSL.

The examiners used the techniques described by Kimura¹⁰ to conduct the tests. Heating pads were used to maintain skin temperature of the hand and wrist at 32°C or greater; however, the actual temperatures were not recorded. Motor nerve studies were obtained for the median nerve by placing the active recording electrode directly over the abductor pollicis brevis muscle with the reference electrode over the proximal phalanx of the thumb, and for the ulnar nerve by placing the recording electrode directly over the

abductor digiti minimi muscle and the reference electrode over the proximal phalanx of the fifth digit. A pair of stimulating electrodes was placed on the wrist over the appropriate nerve with the cathode 7 cm proximal to the recording electrode. Sensory nerve studies were obtained with a ring electrode for recording placed around the proximal phalanx or proximal interphalangeal joint of the 2nd or 3rd digit for the median nerve, and of the 5th digit for the ulnar nerve. Reference ring electrodes were located 3 cm distal to the recording electrodes. A pair of stimulus electrodes was placed on the wrist over the appropriate nerve with the cathode 14 cm proximal to the recording electrode. While these electrode positions differ slightly from those used for the NC-stat, we did not want to force equivalence by altering the typical methodology used by either the reference NCS or the NC-stat. Our goal was to compare the two methods of nerve conduction testing as they would be used in standard practice.

NC-stat Testing

NC-stat testing was performed by 1 of 3 examiners—a medical student, an occupational therapy assistant, and a physical therapy assistant who were trained to operate the device following the manufacturer’s recommendations. They were blinded to the results of the prior traditional NCS. Motor and sensory nerve conduction across the wrist was measured for the median and ulnar nerves on the same arm as the traditional test. Subjects who were tested bilaterally with the traditional method received the NC-stat test on 1 side only. The testing procedure consisted of cleaning the subject’s skin, attaching a “biosensor” (a pre-configured array of stimulating and recording electrodes) to the subject’s wrist and finger, entering the subject’s age, self-reported height, self-reported weight (within a 10 pound range) and study identification number into the NC-

stat, and then activating the device. Stimulus of the nerve and recording of the evoked signals were performed automatically by the device. In cases where an error message or missing data were obtained, the test was repeated once with the current biosensor. If the test was still unable to provide complete results, the biosensor was removed, a new one was attached, and testing was repeated up to 2 more times with the new sensor.

With the biosensor correctly placed, the cathode of a pair of stimulating electrodes was located 3 cm proximal to the distal wrist crease. The electrical potential from the motor response was measured using volume conduction by a pair of electrodes located 1 cm proximal to the distal wrist crease, as opposed to the traditional method of measuring directly over the muscle. This yields a waveform with the same onset time, but a different amplitude and morphology. The sensory response was measured by a pair of ring electrodes, which differ in distance to the stimulating electrode based on the size of the patient's hand. One electrode was placed at the proximal interphalangeal joint of the 3rd (median) or 5th (ulnar) digit and one was located 3 cm (median) or 2 cm (ulnar) distally. Skin surface temperature was measured automatically by a chip embedded in the wrist portion of the biosensor so that it can be recorded and corrected for. The NC-stat also has built in algorithms for automatic determination of supramaximal stimulus intensity and analysis of the evoked responses. It measured the DML based on the time to initial negative deflection, and the DSL based on the time to the negative peak. The technical specifications of the NC-stat unit and of the biosensors have been described in greater detail elsewhere.^{3, 5, 6, 11}

Once NC-stat testing has been performed, the data were stored in the device and were sent electronically via modem to the manufacturer. A report generation system

faxed or emailed back a hard copy of the data within a short period of time (usually within minutes). This report contained measurements including, but not limited to the DML, DSL, motor and sensory MUDs, and the skin temperature at the end of each test. The latencies were reported in 3 different ways: (1) raw data, (2) normalized to a skin temperature of 32°C using a correction factor derived from a proprietary data set, and (3) a percentile score based on age and height-dependent reference ranges for the temperature-adjusted numbers. The manufacturer also provided an interpretation of latencies and median-ulnar latency differences based on their proprietary reference ranges.

Statistical Analysis

All statistical analyses were performed with SPSS software (version 14.0; SPSS Inc, Chicago, IL). Tests were considered statistically significant at the $p < 0.05$ level. We generated receiver-operator characteristic (ROC) curves showing the NC-stat's agreement with a reference standard of the traditional test's result of normal or abnormal. Each point on the curve showed the NC-stat's sensitivity and specificity at a different cutoff for assigning abnormality to its measurements, while the reference standard's cutoff was constant. The smallest NC-stat cutoff value was the minimum observed value minus 1, and the largest cutoff value was the maximum observed test value plus 1. All of the other cutoff values were the averages of two consecutive ordered observed test values. For the DML and DSL, the ROC curves were based on the NC-stat's skin temperature adjusted percentile to account for the height and age variability of the manufacturer's reference ranges for distal latencies. For the motor and sensory MUD, the curves were based on the latency difference of the temperature adjusted values because

the manufacturer's reference ranges were not height and age dependent for these measures. The ROC curves for median and ulnar DSL compared the NC-stat peak DSL to the traditional onset DSL because the reference ranges in the electrodiagnostic lab were based on the onset DSL. The reference ranges used for the traditional NCS were as follows: median DML < 4.4 ms, ulnar DML < 3.5 ms, motor MUD \leq 1.4 ms, median onset DSL < 3.4 ms, ulnar onset DSL < 3.1 ms, sensory MUD \leq 0.7 ms.

A paired t-test was used to compare the mean values of analogous measurements from the two nerve testing methods. We calculated Pearson correlation coefficients and intraclass correlation coefficients (ICCs) between the traditional results and the temperature-adjusted NC-stat results for median and ulnar DML, peak DSL, motor MUD, and sensory MUD. The ICC expanded upon the information provided by the Pearson coefficient by combining a measure of correlation with a measure of agreement.¹² For example, two measures could be perfectly correlated yet have an ICC less than 1 if there is a consistent systematic difference between them.

When nerve conduction latency measurements from either method were absent due to an unresponsive, pathological nerve, the longest latency in the dataset for a corresponding measurement from another subject was substituted for purposes of the ROC analysis. This was because an absent response has the diagnostic significance of neurological abnormality. For the correlation analysis, absent results were excluded. Nerve conduction measurements that were unobtainable for technical reasons were excluded from both analyses. For the traditional NCS, the determination of absent versus unobtainable was the neurologist's assessment after repeated testing. For the NC-stat, this

determination was made by the manufacturer using a computerized analysis of the recorded waveform.

Results

Study Group

Out of 47 eligible patients invited to participate in the study, all of whom had completed traditional testing, NC-stat testing was performed on 34 subjects (72.3%). Of the 13 invited but not tested, 12 refused to participate and 1 halted NC-stat testing after it had been initiated. A group of 33 subjects was used for data analysis because the records of the traditional NCS were missing for 1 individual. The diagnosis being tested for was carpal tunnel syndrome in 25 subjects (75.8%), and the following for 1 subject each: carpal tunnel with cubital tunnel, peripheral neuropathy, median/ulnar neuropathy, ulnar neuropathy, upper extremity paresthesias, elbow pain/numbness, neuropraxia, and C6 radiculopathy. The demographic characteristics of the analytic group are summarized in table 1.

Absent/unobtainable results

Complete results were not obtained in all 33 subjects for all nerve conduction measures (median/ulnar, motor/sensory) from both methods. For median motor studies, the NC-stat could not obtain diagnostic results for 2 subjects and the traditional NCS yielded absent results due to nerve pathology for 1 subject. Both testing methods gave complete results in all 33 subjects for ulnar motor studies. For median sensory studies, both methods recorded absent results in 4 subjects, and an additional 3 results were absent for the NC-stat only. One additional subject had an absent ulnar sensory result for

the traditional test. Unobtainable and absent results were dealt with analytically as described in the methods section.

ROC Analysis

ROC curves depicting the NC-stat's agreement with the traditional test's result of normal or abnormal are shown in Fig. 1. Table 2 shows the number of comparisons for each measurement, the number of abnormal results measured by the reference NCS, and areas under the ROC curves with 95% confidence intervals. For the median DML, DSL, motor MUD and sensory MUD, the areas under the ROC curves were above 0.9. The upper limits of the 95% CIs all included 1 and the lower limits ranged from 0.78 (motor MUD) to 0.94 (sensory MUD). For the ulnar DML and DSL, meaningful ROC curves could not be generated due to insufficient numbers of abnormal results from the reference NCS.

Since each point on the ROC curve is associated with a different cutoff value for assigning abnormality to the NC-stat measurements (data available upon request), along with the sensitivity and specificity with respect to the reference NCS assignment of normal or abnormal, the cutoffs recommended by the manufacturer can be compared to the cutoffs which give the highest combination of sensitivity and specificity. Table 3 shows the approximate sensitivity and specificity of the cutoffs suggested by the manufacturer and of the optimal cutoffs based on the ROC curves. For all parameters the optimal cutoff differed from the manufacturer's suggested cutoff.

Correlations

Scatterplots of NC-stat versus traditional measurements show the association between results (Fig. 2). Table 4 shows the mean values of the NC-stat and reference

measurements and the correlation statistics. All correlations were significant at the $p < .05$ level. Correlations for motor nerve studies were higher than for sensory, and correlations for median nerve distal latencies were higher than for ulnar. With the exception of the ulnar DML, the ICCs had lower values than the Pearson coefficients, reflecting systematic bias due to methodological differences in the two methods of NCS.

Discussion

General

This study demonstrated good categorical agreement between NC-stat measurements and traditional measurements of the median nerve at the wrist, indicating a potential role for the NC-stat to expand use of NCS in appropriate settings. However, the exact settings in which the NC-stat is most suitable for use have yet to be determined. In this study, we attempted only to show how the measurements obtained with the NC-stat compare with analogous measurements obtained traditionally, not to evaluate how well physicians can assign clinical relevance to the results. We did not address additional limitations of the NC-stat such as lack of a needle EMG examination. Whatever method used for nerve conduction testing, such testing can aid in making a clinical diagnosis but is not sufficient to make a diagnosis alone. Nerve conduction data must be incorporated into the overall clinical picture and combined with all other available information.

ROC Analysis

Areas under the ROC curves for median nerve measurements were near 1, indicating a high level of agreement between the NC-stat's results and the results of the reference NCS for the median DML, DSL, and motor/sensory MUD. Combining

information from the median nerve distal latencies and MUDs, the ROC data suggests that the NC-stat could attain sensitivity of up to 100% and specificity greater than 90% for both motor and sensory studies of the median nerve at the wrist. Since most of the subjects (75.8%) were referred for electrodiagnosis of carpal tunnel syndrome and not ulnar nerve pathologies, almost all had normal ulnar nerve function as measured by the reference NCS. This made the ROC analysis uninformative when looking at the ulnar nerve alone.

The manufacturer's suggested abnormality thresholds for NC-stat measurements give results that appear biased towards sensitivity with some sacrifice in specificity for the median DML, motor MUD, and sensory MUD. The median DSL actually appears biased in the opposite direction, but this result is difficult to interpret given the abnormal shape of its ROC curve. The NC-stat's overall bias towards sensitivity has several possible explanations. The first is simply that its operating point is not completely optimized. Alternatively, the bias toward sensitivity could have to do with the thresholds used for the traditional NCS in this study. If the traditional NCS used conservative thresholds tending towards specificity, this would also make the NC-stat look more sensitive and less specific. The age and height adjustment of the NC-stat distal latency reference ranges is another important issue to consider. Since the traditional NCS used the same cutoffs for all demographic groups, the demographic characteristics of this study's population had an influence on the NC-stat's apparent operating characteristics. For example, when compared against a fixed reference standard the NC-stat will appear more sensitive and less specific for young and short subjects, and less sensitive and more specific for older and taller subjects. The false positive and false negative rates of the

NC-stat in comparison to the reference standard must also be interpreted in light of the fact that two neurologists using identical methods also have imperfect agreement.¹³

Therefore, the observed lack of agreement cannot truly be assigned entirely to the NC-stat.

Correlations

NC-stat median nerve distal latencies correlated well with traditional NCS, while ulnar distal latencies did not. Prior studies comparing the NC-stat to traditional NCS have shown Pearson correlation coefficients of 0.90-0.96 for median DML,³⁻⁵ 0.7 for ulnar DML,⁵ 0.91 for median DSL,⁶ and 0.7 for ulnar DSL.⁶ One prior study also looked at the ICC between the NC-stat and traditional NCS, finding a value of 0.91 for the median DSL and 0.69 for the ulnar DSL.⁶ The correlations obtained in this study for median nerve distal latencies are slightly lower but comparable to previous reports, while the ulnar correlations are substantially lower. This is likely due to the small range (about 1 millisecond) of ulnar DML and DSL values measured among our study group. Because all of the values fell within such a compact range, the correlations were smaller than they might be if looking at a wider range of abnormal values.⁸ The lack of variability in ulnar nerve latencies is a reflection of the previously mentioned low prevalence of ulnar nerve pathology in our study group. The other factor lowering median and ulnar correlations in our study was variability within both NCS methods. The traditional NCS were not all performed by the same neurologist or technician, and several different types of equipment were used. Similarly, the NC-stat testing was carried out by 3 different examiners. Despite the low ulnar correlations, the MUDs had high correlations, indicating that the ulnar latency measurements were valid within the individual patients.

Correlations between the NC-stat and traditional methods of NCS are similar in magnitude to the correlations obtained in the assessment of inter-examiner and test-retest reliability of traditional NCS. A study looking at the inter-examiner reliability of traditional NCS between examiners using identical methodology but different equipment found a Pearson coefficient and ICC of 0.91 for the median peak DSL and a Pearson coefficient of 0.64 and an ICC of 0.63 for the ulnar peak DSL. The same study also evaluated the test-retest reliability of the same examiners, finding Pearson correlations from 0.82-0.92 and ICCs from 0.80-0.92 for the median peak DSL and Pearson correlations from 0.37-0.47 and ICCs from 0.33-0.43 for the ulnar peak DSL.¹³ It is notable that this reliability assessment of traditional NCS methods also found lower correlations for the ulnar nerve than for the median nerve. This suggests an intrinsic difficulty with replicating ulnar nerve measurements, regardless of the testing device used.

Limitations

Several limitations must be taken into account when interpreting the findings of this study. First, the extent to which the results can be generalized may be limited. The sample size was only 33 subjects, and almost all of them had normal ulnar nerve conduction at the wrist. Women were also over-represented in the study population, accounting for 66.7% of the participants. Additionally, out of the 47 patients invited to participate in the study, 13 (27.7%) declined. Although unlikely, it is possible that different results could have been found among the non-participants. A limitation of the ROC analysis is that comparison was against only one reference standard rather than the consensus of several expert examiners testing the same subject. An additional limitation

of this study is the variation within each of the two testing methods: the reference NCS were not all performed by the same examiner or equipment and the NC-stat testing was not all by one examiner either. Therefore, the observed agreement between testing methods was probably lower than it would have been in a more controlled situation. Instead, our study more closely mirrors clinical practice, where physicians may receive nerve testing results from different testers using different devices. Finally, the traditional method of NCS used as the reference standard in this study did not fully account for age, height, and skin temperature as covariates for nerve conduction velocity – this is again similar to the situation commonly found in clinical practice.

Conclusions

Our data support the conclusion that the NC-stat has good criterion validity for testing the median nerve at the wrist. The reference ranges currently provided by the NC-stat's manufacturer may need to be adjusted for different populations. This issue is shared with traditional NCS. While the NC-stat is not designed to replace traditional methods of NCS, it may be a useful supplement in settings where distal latency measurements are of primary interest. For example, the device may be well suited for applications such as field-based research studies or carpal tunnel syndrome screening among symptomatic patients. However, in many clinical situations referral to a specialist for a more comprehensive evaluation would be prudent. This data set was insufficient for a conclusion to be drawn regarding the use of the NC-stat for testing the ulnar nerve at the wrist.

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Figure Legends

Fig. 1. ROC curves for median nerve studies and median-ulnar latency differences. The NC-stat at various abnormality thresholds was compared against a reference standard of the traditional NCS result of normal or abnormal.

Fig. 2. Scatterplots of corresponding distal latency measurements and median-ulnar latency differences between NC-stat and traditional nerve conduction testing.

Figure

Figure 1

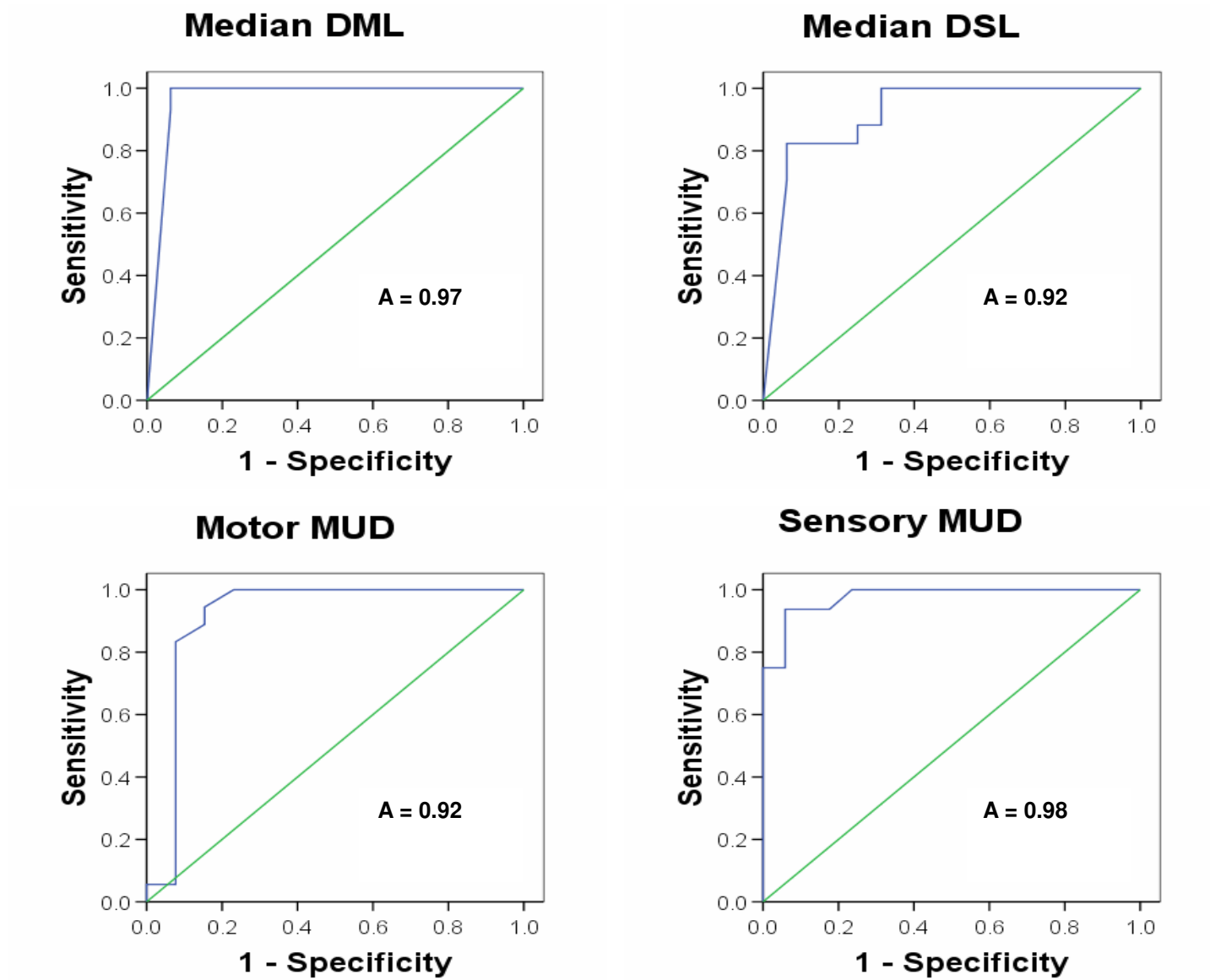


Figure 2

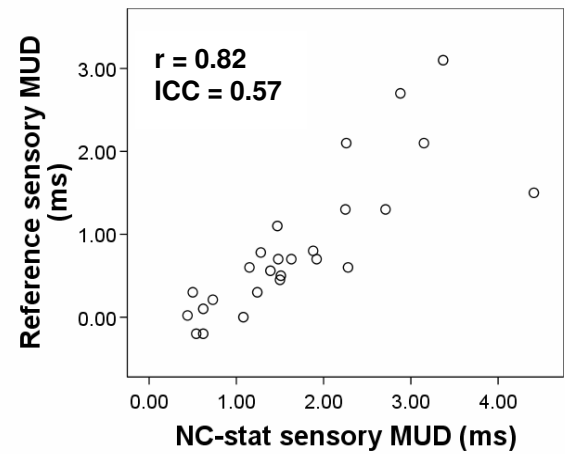
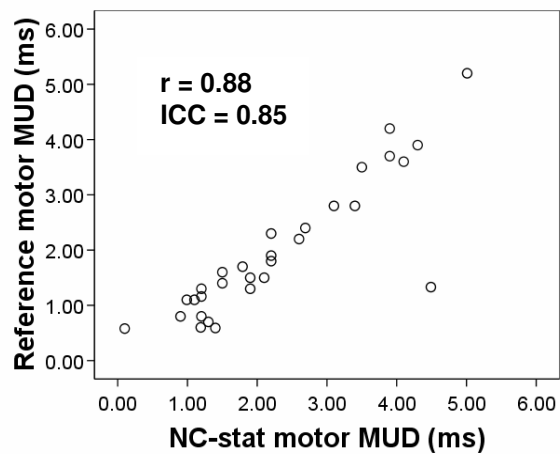
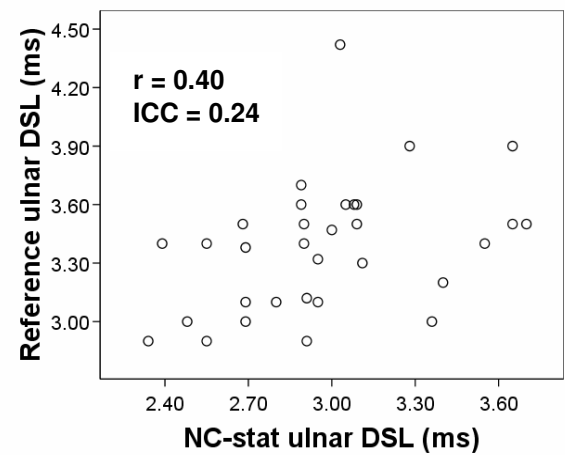
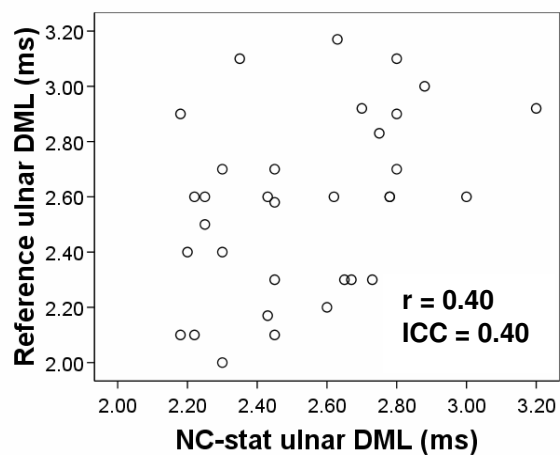
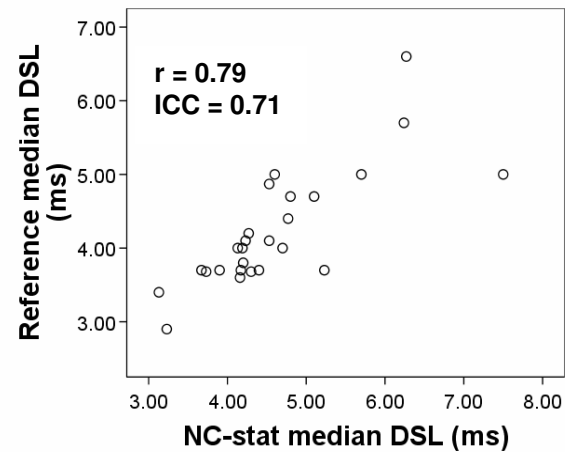
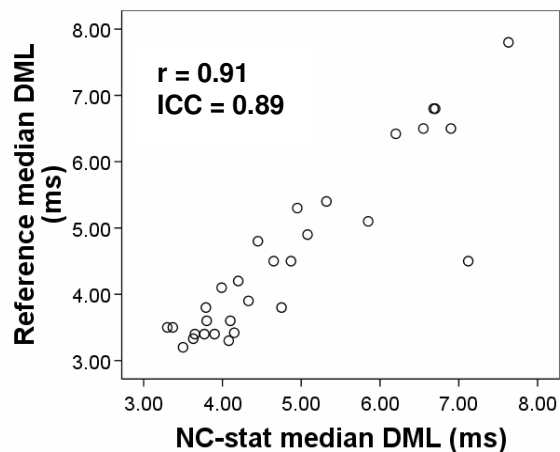


Table 1. Demographic characteristics of the study group.

Number of Subjects	33
Female (%)	66.7%
Mean Age (y)	51.6 (SD 12.9)
Mean Height (cm)*	167.3 (SD 11.4)
Mean BMI (kg/m ²)*	29.7 (SD 6.8)

Abbreviations: SD, standard deviation; BMI, body mass index

*Height and weight self-reported by subjects

Table 2. Properties of the receiver-operator characteristic (ROC) curves.

Measurement	No. of Comparisons	Reference NCS No. Abnormal	Area Under ROC Curve	95% CI for Area
Motor nerve				
Median DML	31	15	0.97	0.91-1.00
Ulnar DML	33	0	NA	NA
MUD	31	18	0.92	0.78-1.00
Sensory nerve				
Median DSL	33	17	0.92	0.82-1.00
Ulnar DSL	33	2	NA	NA
MUD	33	16	0.98	0.94-1.00

Abbreviations: NCS, nerve conduction studies; ROC, receiver-operator characteristic; CI, confidence interval; DML, distal motor latency; DSL, distal sensory latency; MUD, difference between median and ulnar latencies

Table 3. Sensitivities and specificities of NC-stat measurements with respect to the reference NCS. The manufacturer's suggested cutoff is compared to the optimal cutoff based on the ROC data.

Measurement	Suggested Cutoff	Sensitivity	Specificity	Optimal Cutoff	Sensitivity	Specificity
Median DML	97.5 th percentile	100%	81.2-87.5%	98.9 th percentile	100%	93.7%
Motor MUD	1.34 ms	100%	61.5-69.2%	1.65 ms	94.1%	84.6%
Median DSL	97.5 th percentile	88.2%	68.7-75%	96.6 th percentile	100%	68.7%
Sensory MUD	1.14 ms	100%	41.2-47.1%	1.75 ms	93.8%	94.1%

Abbreviations: NCS, nerve conduction studies; ROC, receiver-operator characteristic; CI, confidence interval; DML, distal motor latency; DSL, distal sensory latency; MUD, difference between median and ulnar latencies

Table 4. Average values for the reference and NC-stat measurements and correlations between the two sets of measurements.

Measurement	No. of Valid Comparisons	Reference Mean (SD)	NC-stat Mean (SD)	P* Value	Pearson r (95% CI)	ICC (95% CI)
Motor nerve						
Median DML	30	4.6 (1.3)	4.8 (1.3)	.015	.91	.89
Ulnar DML	33	2.6 (0.3)	2.5 (0.3)	.564	.40	.40
MUD	30	2.0 (1.2)	2.3 (1.3)	.009	.88	.85
Sensory nerve						
Median peak DSL	26	4.2 (0.8)	4.6 (1.0)	.004	.79	.71
Ulnar peak DSL	32	3.4 (0.3)	3.0 (0.4)	<.001	.40	.24
MUD	26	0.9 (0.9)	1.7 (1.0)	<.001	.82	.57

Abbreviations: SD, standard deviation; ICC, intraclass correlation coefficient; DML, distal motor latency; DSL, distal sensory latency; MUD, difference between median and ulnar latencies