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QUANTITATIVE EEG AND THE FRYE AND DAUBERT STANDARDS OF ADMISSIBILITY

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Abstract

The seventy year old *Frye* standards of "general acceptance" were replaced by the Supreme Court's 1993 *Daubert* criteria of the scientific method, which established the standards for admissibility of evidence in Federal Court. The four *Daubert* criteria were: 1- Hypothesis testing, 2- Estimates of error rates, 3- Peer reviewed publication and 4- General acceptance (*Daubert v. Merrell Dow Pharmaceuticals*, 61 U.S.L.W 4805 (U.S. June 29, 1993)). The present paper starts with the *Daubert* four factors and then matches them, step by step, to the scientific peer reviewed literature of quantitative EEG (QEEG) in relation to different clinical evaluations. This process shows how the peer reviewed science of the Digital EEG and the Quantitative EEG (QEEG) meet all of the *Daubert* standards of scientific knowledge. Furthermore, the science and technical aspects of QEEG in measuring the effects of neurological and psychiatric dysfunction also matches the recent Supreme Court standards of "technical" and "other specialized" knowledge (*General Electric Co v. Joiner, 1997*; *Kumho Tire Company, Ltd. v. Carmichael, 1999)* . Finally, it is shown that QEEG scientific knowledge and QEEG "technical" and "other specialized" knowledge meet the trilogy standards of the Supreme Court rulings in support of QEEG's admissibility as a clinically valid method in the evaluation of the nature and extent of neurological and psychiatric disorders.

Key words: *Daubert*/ *Frye*, QEEG, Expert Testimony

1.0 – Introduction

Nuwer (1) as a spokesperson for the American Academy of Neurology (AAN) wrote a position paper that argued that the quantitative electroencephalography or QEEG is scientifically valid and represents a clinically important tool for the evaluation of many neurological disorders (e.g., strokes, dementia, epilepsy, intraoperative monitoring). However, in contradiction to the clinical endorsement of QEEG in the body of the AAN paper (1) the last section of the paper argued that a patient's billable medical record of QEEG should not be allowed as evidence in a courtroom. It appears that in the otherwise well thought out 1997 AAN position paper that endorsed third party billing of QEEG as a standard of care in the evaluation of dementia, strokes, epilepsy and intraoperative monitoring (1), at the same time, wrongly denied the admissibility of a patient's QEEG in a court of law. This contradiction, which denies patient's rights to scientifically valid technology and their own medical records was likely an oversight or unchecked error. The AAN is encouraged to revisit the medical-legal issues with a goal to produce a new position paper that retains the best features of the 1997 paper but interprets the admissibility of QEEG much more in line with the Supreme Court's standards of science espoused by Nobel laureates and the American Academy of Sciences in the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals* (2) and the subsequent standards of admissibility in *Kumho v. Tire Company, Ltd. v. Carmichael* (3). In an effort to clarify the law as it applies to the science of QEEG this paper will review the Supreme Court's rulings and then, step by step, apply the standards espoused by the Supreme Court to the quantitative EEG.

1.1 – Background of Frye and Daubert

Since 1923 the *Frye* test held that expert testimony that is based upon a scientific technique is inadmissible unless the technique is "generally accepted in the scientific community" (4). By 1970 the *Frye* standard for expert opinion allowed "Pseudoscientific" testimony (such as Nuwer and the ANN (1)) to have equal weight to "Scientific" testimony and the advance of modern technology

compelled the Court to revisit *Frye* in 1993. The Court in *Daubert* had the benefit of amicus briefs from 13 Nobel Laureates and the American Academy of Science and many other scientific organizations. The Court in *Daubert* replaced *Frye* by four factors or criteria to define the "Scientific Method": 1- hypothesis testing, 2- estimation of error rates, 3- peer reviewed publications and, 4- general scientific acceptance. Pseudoscientific methodology was not rejected, per se, only the standards in which there was insufficient connection between knowledge was rejected. *Daubert* had only one dissenting opinion, which concerned the fact that there is a language gap between a lawyer's and Judge's knowledge of scientific language and legal language. Justice Rehnquist: while he has great respect for federal judges stated, "I am at a loss to know what is meant when it is said that the scientific status of a theory depends on its 'falsifiability,' and I suspect some of them will be, too". The recent Supreme Court ruling in *Kumho* 1999 (3) which added to *Daubert* was, in part, a response to Justice Rehnquist's dissenting opinion that the jury, and not a judge, is the best arbiter of admissibility of evidence.

1.2 - Language Mismatch Between Law and Science

One of the difficulties for the legal profession regarding *Daubert* is that *Daubert* is based on scientific language and principals and explicit scientific standards that are couched in terms largely unfamiliar to the legal profession. As mentioned in section 1.1, the language in the Supreme Court's *Daubert* ruling benefited from amicus briefs from the American Association for the Advancement of Science and the National Academy which articulated "the scientific method" a term used in the scientific community that defines hypothesis testing as a method of testing scientific theories by posing individual hypotheses about questions of interest and then testing to see if these hypotheses can be confirmed as being true. *Daubert* referred to statistical standards of error rates to reject an hypothesis at a given *alpha* level but gave discretion for the choice of the *alpha* level up to the expert to reject the null hypothesis (see the amicus brief of the American

Association for the Advancement of Science and the National Academy of Sciences (2)).

1.3 – *Frye* Evolution to *Daubert*

Frye defined the evidentiary issue for admissibility as “reliability” and then deferred to an undefined "scientific community" for its "general acceptance" and used, in a circular logic, general acceptance as the basis for “reliability”. The Supreme Court in *Daubert* still recognized the importance of “general acceptance” as an indicator of evidentiary reliability but it went further and defined general acceptance in two ways. First, it addressed the defining characteristic of the scientific community as a community that relies upon peer reviewed publications. Second, it recognized that the scientific method is the standard used across different branches of science and it specifically required that admissible evidentiary science be grounded in a basic scientific structure. For example, the Supreme Court in *Daubert*, stated that in order for expert testimony to be admissible: "the subject of an expert's testimony must be scientific . . . knowledge, because it is the requirement that an expert’s testimony pertain to scientific knowledge that establishes a standard of evidentiary reliability. But, in order to qualify as scientific knowledge, an inference or assertion must be derived by the scientific method . . . .". (2) (Justice Blackmum, at 4808 to 4811). The majority opinion of the Supreme Court in *Daubert* concluded that only scientific knowledge can be offered as expert testimony, and the Court regarded as scientific knowledge only that which is derived by the scientific method.

1.4 – Majority Opinion Quotations From *Daubert*

The following are quotations of the words of the majority opinion expressed by Justice Blackmum (2) “That the Frye test was displaced... does not mean, however, that the Rules themselves place no limits on the admissibility of purportedly scientific evidence. Nor is the trial judge disabled from screening such evidence. To the contrary, under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable”.

Justice Blackmun also noted that "scientists do not assert that they know what is immutably 'true' -- they are committed to searching for new, temporary theories to explain, as best they can, phenomena" and that science "represents a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement.". Thus, judges make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Jurors determine the credibility of what survives. Finally, to answer Frye proponents, Justice Blackmun stated: "We conclude by briefly addressing what appear to be two underlying concerns.... Respondent expresses apprehension that abandonment of "general acceptance"... will result in a "free-for-all" in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions. In this regard respondent seems to us to be overly pessimistic about the capabilities of the jury, and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." (2).

2.0 - The Scientific Method and Daubert's Four Factors for Admissibility of Expert Testimony

2.1 - *Hypothesis testing:* Mahle in a succinct review of *Daubert* (5) summarized scientific hypothesis testing as: "Hypothesis testing is the process of deriving some proposition (or hypothesis) about an observable group of events from accepted scientific principles, and then investigating whether, upon observation of data regarding that group of events, the hypothesis seems true.". Stephen Mahle, Ph.D. and a LLD (5) demonstrates how to bridge the language gap between law and science by providing a simple example of hypothesis testing which adequately demonstrates the process:

> "*A simple example of hypothesis testing:* Looking at a single six-sided die might lead one to the proposition (or hypothesis) that

> each of the six numbers is equally likely to be rolled on each roll of the die. This hypothesis is tested scientifically by proposing the "null hypothesis" that each number is equally likely to land face up, and then rolling the die (say) 600 times and recording the number of times that each number is actually found face up. If an appropriate statistical test is used, and if each number occurred about 100 times, the statistical test will be unable to reject the null hypothesis of equal probabilities, and the scientist will be left with the likelihood that the die is fair. However, if the number '3' occurs a disproportionate number of times, say 200 times out of 600 rolls, then the statistical test will be likely to reject the null hypothesis of equal probabilities and the scientist will interpret this as evidence that the die is loaded and reject the null hypothesis." (5).

The "Null Hypothesis" is a statistical concept by which a distribution of measurements (samples) are objectively determined to be either consistent or inconsistent with the hypothesis or theory. A statistical hypothesis is usually a statement about one or more population distributions. The statement is called a hypothesis because it refers to a situation that *might* be true and can be rejected by rejecting the null hypothesis. Scientific hypotheses about the nature of a phenomena or the underlying bases are linked to the statistical distributions used to test the hypothesis. The Gaussian distribution or "Bell Shaped" curve is fundamental to much of physical and social science, for example, Gaussian wavepackets in quantum mechanics (6), the Wavelet 'Mexican Hat' is the second derivative of the Gaussian curve, the Wavelet 'Morlet' is the Gaussian envelope of a sine wave (7). The electrical potential of the human brain (QEEG) is measured in microvolts with respect to a reference and it can be accurately approximated by transforms to a Gaussian curve or the "Bell Shaped" curve, especially for large groups of subjects such as in a reference QEEG database (8 – 13 and 27 - 34).

2.2 - *The known or potential error rate:* The second *Daubert* factor involves evaluating the scientific validity and reliability of "purported scientific testimony" which requires understanding the "known or potential rate of error" associated

with using the particular scientific technique. Again quoting from the Florida Law Bar Review, Mahle (5):

> "There are two types of error rates in testing hypotheses and they are denoted as "Type I error" and "Type II error." Type I error is the test's propensity for false positives while Type II error is the test's propensity for false negatives. For example, if a drug test for a substance comes back positive, but the tested individual has not actually used the drug, a lay person would call that a false positive, while a scientist would call it a Type I error. This Type I error is the most commonly cited component of the "error rate" in hypothesis testing. This error rate is also known both as the "level of confidence" of the hypothesis test and as the level of statistical significance of the test's result. Determining this error rate is actually part of conducting an hypothesis test. A common assertion in scientific research is that "the null hypothesis is rejected at the 1% level," or equivalently "the result is statistically significant at the 1% level," which means that the statistical technique used to test the hypothesis, if applied to data where the null hypothesis is true, would reject the null hypothesis only 1% of the time. If such a statement were made about the example of the single die above, it would mean that if the die were not loaded and the experiment of rolling it 600 times and testing the null hypothesis that the die was fair were done 100 times, 99 of those tests would correctly show the die to be fair, while 1 of those tests would incorrectly show the die to be loaded."

Statistical hypothesis testing about the distribution of a population is again a fundamental aspect of the estimation of error rates. A "Gaussian" or "Bell Shaped" distribution, for example, provides a direct estimate of the number of events expected to occur in the tails of the distribution and the Bell Shaped curve is one of the most common population distributions used to accept or reject the null-hypothesis as well as to estimate the error rates The last 30 years of neuroscience has consistently demonstrated that with simple transforms the vast majority of EEG microvolt measurements from a population of individuals approximate a Gaussian distribution (13, 27 - 34).

2.3 - *Peer review and publication:* The third *Daubert* factor or criteria in determining whether expert testimony is admissible at trial is "whether the theory

or technique has been subjected to peer review and publication."(2). Again quoting from Mahle (5):

> "Publication is typically the purpose for which research is offered up for peer review and passing the peer review is required for publication. "Peer review and publication" of a scientist's work is largely a term of art that means that the scientist's peers have sanctioned the work as credible and accepted it for publication. Publication then exposes the work to further review by other scientists whose responses to the research indicate their agreement or disagreement with the methods and results of the work."

2.4 - *General Acceptance:* The fourth Daubert criterion or factor reflects the extent to which the expert's methods produce information that qualifies as scientific knowledge.

> "Scientific methods begin the process of becoming generally accepted in the scientific community by bringing appropriate hypothesis testing techniques to bear on questions (or hypotheses) of interest to the scientific community in a fashion that results in the peer approval required for publication. They move toward general acceptance by then withstanding the scrutiny of the broader scientific community to which publication exposes the methods." (5).

It is important .to emphasize that "general acceptance" or "relevant scientific community" do not refer to a collection of individuals who simply assert opinions such as an organization like the American Academy of Neurology in which position papers are published (1) without citing the peer reviewed literature of facts that underlay the clinical reliability and validity of 20 years of QEEG (13 – 15, 19 - 26). Also the National Library of Medicine is an excellent source of citations to peer reviewed literature of the clinical applications of QEEG, try using the search words QEEG and a clinical disorder of interest at: www.ncbi.nlm.nih.gov/entrez/query.fcgi.

3.0 –Broadening of *Daubert* by *General Electric Co. v. Joiner* in 1997 and *Kumho v. Carmichael* in 1999

The Supreme Court revisited *Daubert* in 1997 (3) and 1999 (16) and broadened the strict requirement of "scientific" knowledge in *Daubert* regarding admissibility of evidence by expert witnesses to include "technical" and "specialized" knowledge. The Court held in *General Electric v Joiner* that a trial judge need not accept expert testimony "which is connected to existing data only by the unproven assertion of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered". A more significant ruling by the Supreme Court in *Kumho v. Tire Company, Ltd. v. Carmichael* held that "*Daubert's* general holding . . . applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." (16). The Court in *Kumho* added two adjectives, in addition to "scientific" to the central concept of knowledge: 1- "technical" and 2- "specialized other" knowledge. *Kumho* echoed Justice Rehnquist's dissent in *Daubert* and the majority opinion written by Justice Breyer expressed the view that it would be "difficult for judges to distinguish scientific from non-scientific testimony and that there is no clear line dividing the one from the other." The *Kumho* ruling extended *Daubert* to include expert knowledge in which the credibility of that knowledge is to be judged by a jury in which experts use science, specialized and other methods of coming to their conclusions. In *Kumho* the Court indicated that all expert witnesses should use "in the courtrrom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." QEEG is a specialized science that meets both the *Daubert* and *Kumho v. Carmichael* standards and, as is reviewed below therefore meets the standards of law in *Daubert and Kumho* . It will be demonstrated how QEEG must be admitted as evidence at trial because both sides at trial have a fundamental right for a jury of their peers to hear expert testimony to render a decision based on the facts presented at trial.

4.0 – How QEEG Meets the Four *Daubert* Factors

4.1 – Definition of Digital EEG and QEEG

Digital EEG are digital samples of the electrical potentials produced by the brain, referred to as the electroencephalogram or EEG. The electrical potentials of the brain also produce magnetic fields that are at right angles to the electrical fields recorded at the scalp with respect to a reference point, usually the ear or linked ears. Nuwer in the position paper for the American Academy of Neurology defined "Quantitative EEG (QEEG) as: "the mathematical processing of digitally recorded EEG in order to highlight specific waveform components, transform the EEG into a format or domain that elucidates relevant information, or associate numerical results with the EEG data for subsequent review or comparison." (1) (at p. 278). Comparisons to normative values was defined by Nuwer as: "group statistics to determine whether a parameter (or parameters) measured on an individual patient lies inside or outside the range of normal values. Statistical techniques employed may be simple thresholds based on the mean and standard deviation of a "normal" distribution. More advanced techniques may encompass age-adjusted norms, Bayesian statistics, etc." ((1), p. 279).

4.2– Hypothesis Testing of the Reliability of QEEG

Reliability concerns the extent to which any measuring procedure yields the same results on repeated trials. The measurement of any phenomenon always contains a certain amount of chance error. The null hypothesis in any test of reliability is where reliability = 0, that is, repeated measurements of the same phenomenon never duplicate each other and they are not consistent from measurement to measurement. The Type I and Type II errors inherent in the reliability of a sample of digital EEG and/or QEEG can be measured in different ways. An acceptable level of reliability is less than ± 5% inconsistency of repeated measurements of the same phenomena.

There are various ways to measure reliability such as the retest method, alternative-form method, and split-halves method (17). The particular method of computing reliability may depend on the circumstances or personal choice. In the case of the QEEG there have been numerous papers published in peer reviewed journal articles involving a wide number of different reliability measures (18 - 26). These studies have shown that the average test re-test reliability of 60 second samples of artifact free EEG in the hands of a competent person is > 0.9.

4.3 – Suggestions for Expert Witnesses: Document QEEG Reliability

Documentation of the reliability of QEEG measures is important in any evidentiary hearing regarding the admissibility of the QEEG. The plaintiff or defense attorney should ask that all expert witnesses produce documents showing the reliability of the QEEG samples that were used to evaluate the EEG of a client. Reliability is a critical factor in both Frye and Daubert hearings and figure one is an example of the type of reliability documentation that can be provided by a QEEG expert witness if the attorney asks for it (if you don't ask then you will likely not receive the exhibits and facts needed to win your case).

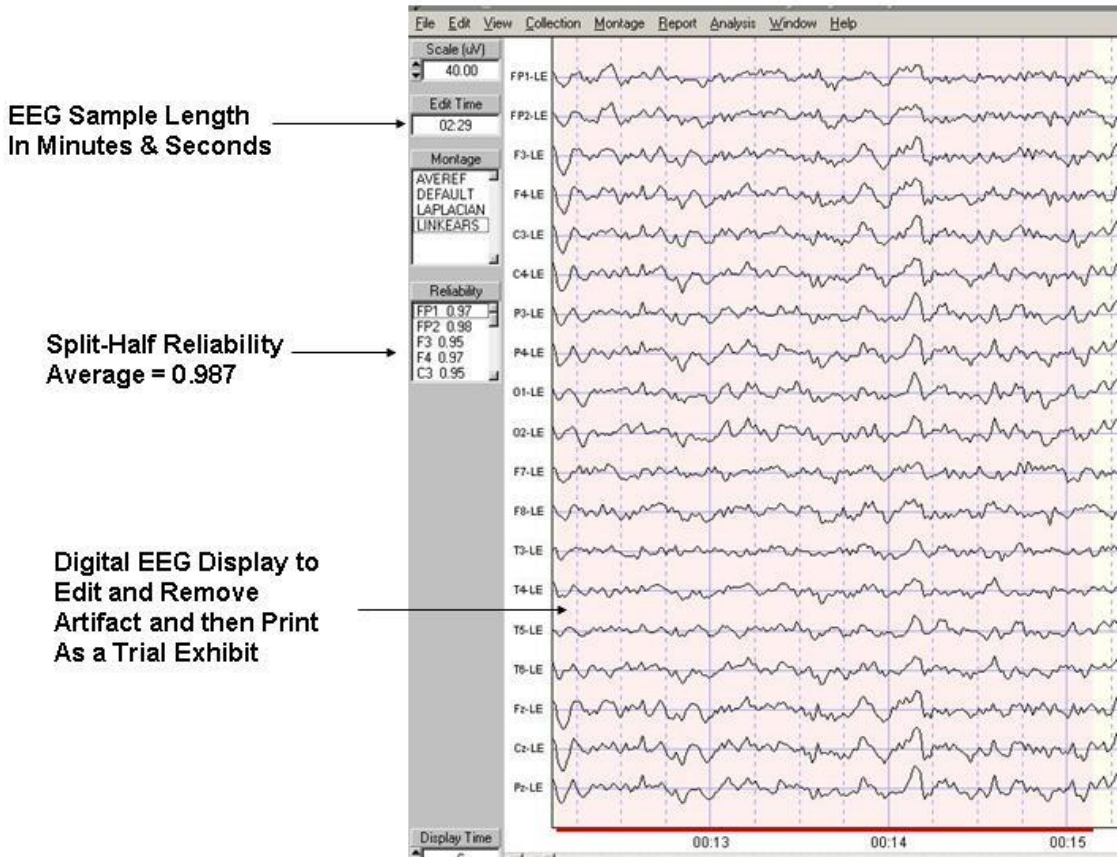


Fig. 1 is an example of dynamic and real-time split-half reliability measures of the QEEG in which the variance of even and odd 1 second samples of EEG were computed using a standard reliability statistic (17).

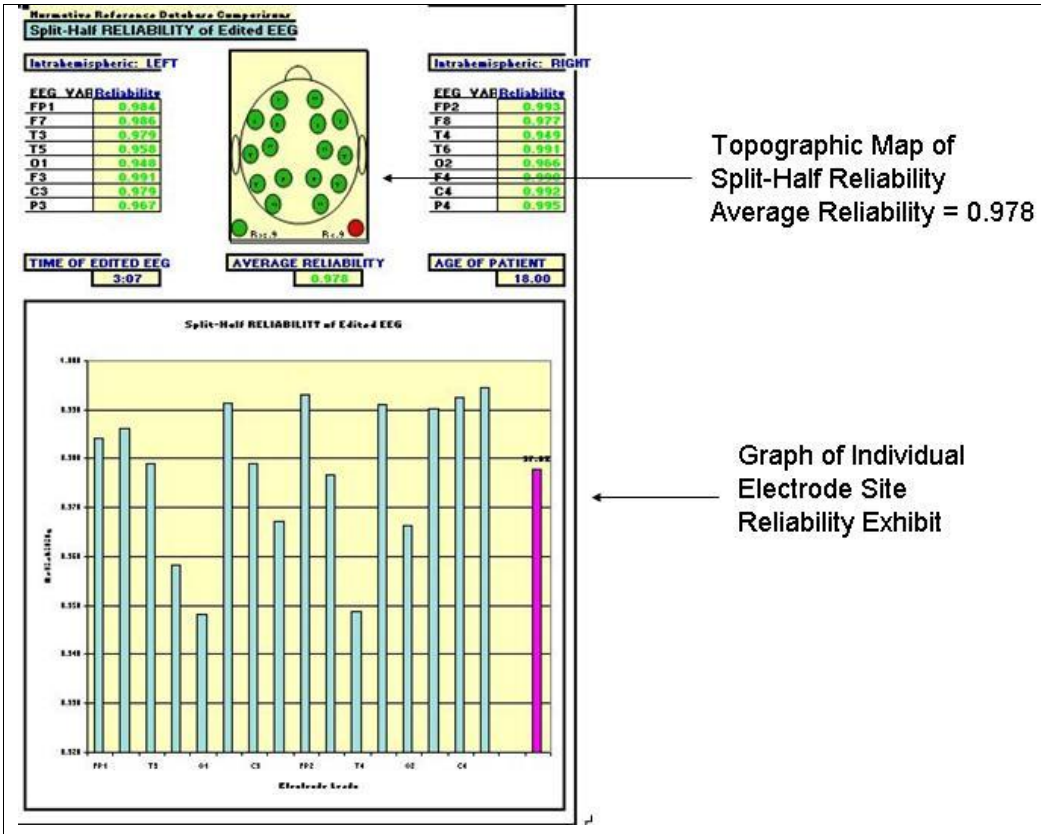


Fig. 2 – An example of a Excel report documenting the split-half reliability of the EEG and demonstrating rejection of the null hypothesis.

4.4 – Hypothesis Testing and qEEG Normative Data Bases

The Gaussian or Normal distribution is an ideal bell shaped curve that provides a probability distribution which is symmetrical about its mean. Skewness and kurtosis are measures of the symmetry and peakedness, respectively of the gaussian distribution. In the ideal case of the Gaussian distribution skewness and kurtosis = 0. In the real world of data sampling distributions skewness and kurtosis = 0 is never achieved and, therefore, some reasonable standard of deviation from the ideal is needed in order to determine the approximation of a distribution to Gaussian. The primary reason to approximate "Normality" of a distribution of EEG measures is that the sensitivity (i.e., error rate) of any normative EEG database is determined directly by the shape of the

sampling distribution. In a normal distribution, for example, one would expect that approximately 5% of the samples will be equal to or greater than ± 2 standard deviations and approximately 1 % ± 3 SD. (25, 27 – 35).

A practical test of the sensitivity and accuracy of a database can be provided by cross-validation. There are many different ways to cross-validate a database. One is to obtain independent samples and another is to compute Z scores for each individual subject in the database. The former is generally not possible because it requires sampling large numbers of additional subjects who have been carefully screened for clinical normality without a history of problems in school, etc. The second method is certainly possible for any database. Gaussian cross-validation of the EEG database used to evaluate TBI was accomplished by the latter method in which Z scores were computed for all variables from each individual subject based on his/her respective age matched mean and SD in the normative database. A distribution of Z scores for each of the EEG variables for each subject was then tabulated. Figure 3 is an example of the Gaussian

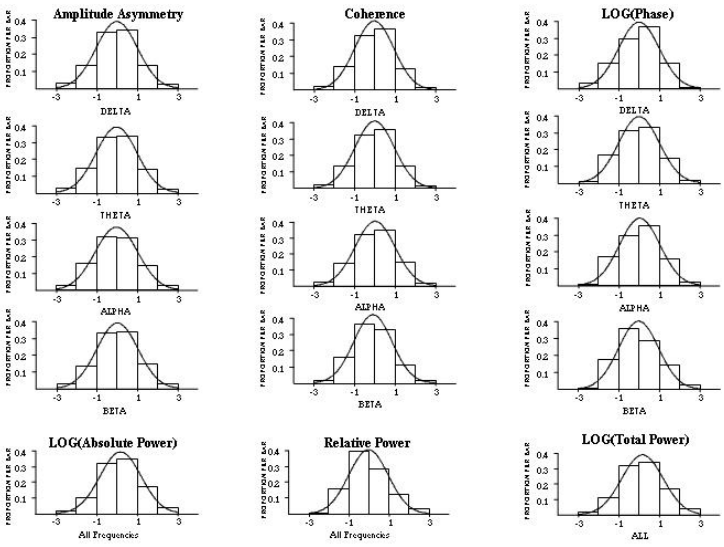


Fig. 3 – Example of Gaussian Cross-Validation of EEG Normative Database

distributions of the cross-validated Z scores of 625 subjects from birth to 82 years of age used in a normative EEG database (33 – 34).

Table I: Cross Validation of EEG Normative Database

Measure	% >2 SD	% <2 SD	% >3 SD	% <3 SD
Delta Amplitude Asym.	2.58	3.08	0.21	0.19
Theta Amplitude Asym.	2.29	2.62	0.15	0.13
Alpha Amplitude Asym.	2.71	2.72	0.18	0.19
Beta Amplitude Asym.	2.68	2.65	0.15	0.15
Delta Coherence	1.99	2.14	0.14	0.22
Theta Coherence	2.22	1.88	0.22	0.16
Alpha Coherence	2.55	1.62	0.18	0.18
Beta Coherence	2.20	1.38	0.18	0.10
Delta Phase †	0.89	3.52	0	0.23
Theta Phase †	1.61	1.87	0.04	0.13
Alpha Phase †	1.61	1.66	0.04	0.24
Beta Phase †	2.83	0.72	0.27	0.03
Absolute Power †	4.15	1.67	0.23	0.12
Relative Power	4.09	0.52	0.68	0
Total Power †	4.23	1.60	0.08	0.04
Average	2.58	1.98	0.18	0.14

† Data was logged transformed

Table I shows the results of a Gaussian cross-validation of the 625 subjects in the normative EEG database used in the evaluation of patients. A perfect cross-validation would be 2.3% at + 2 S.D., 2.3% at – 2 S.D., 0.13% at + 3 S.D. and 0.13 % at – 3 S.D. Table I shows a cross-validation grand average of 2.28% ± 2 S.D. and 0.16 % ± 3 S.D. The cross-validation result shows that the EEG normative database is statistically accurate and sensitive with slight differences between variables that should be taken into account when evaluating individual Z scores.

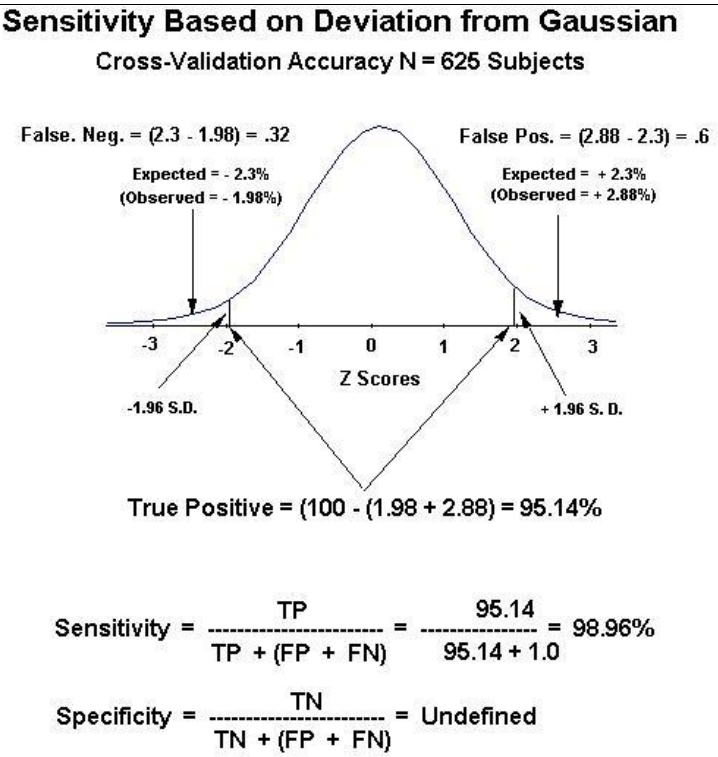


Fig. 4 - Illustration of method of computing error rates or sensitivity of a normative EEG database based on the cross-validation deviation from Gaussian.

Figure 4 is a bell shaped curve showing the ideal Gaussian and the average cross-validation values of the EEG normative database used to evaluate patients. The error rates or the statistical sensitivity of a QEEG normative database are directly related to the deviation from a Gaussian distribution. Figure 4 illustrates the method of estimating the statistical sensitivity of a normative EEG database in terms of the deviation from Gaussian.

Table II is an example of the calculated sensitivity of a EEG normative database for different age groups using the method described in figure 4.

FFT Normative Database Sensitivities

2 STDEVs	CALC SENSITIVITY: FP=TP/(TP+FP) or FN=TP/(TP+FN)			
AGES	(+/- 2 SD)	(>= 2 SD)	(<= -2 SD)	
0-5.99	0.95448265	0.9771774	0.97730526	
6-9.99	0.95440363	0.9772031	0.97720054	+/- **2 Std. Dev.**
10-12.99	0.9543997	0.97724346	0.97715624	
13-15.99	0.95440512	0.97723601	0.97716911	
16-ADULT	0.9543945	0.97718143	0.97721307	
ALL	0.95442375	0.97720714	0.97721661	

3 STDEVs	CALC SENSITIVITY: FP=TP/(TP+FP) or FN=TP/(TP+FN)			
AGES	(+/- 3 SD)	(>= 3 SD)	(<= -3 SD)	
0-5.99	0.99743898	0.99871123	0.99872774	
6-9.99	0.99744112	0.99871611	0.99872501	+/- **3 Std. Dev.**
10-12.99	0.99744688	0.99873171	0.99871518	
13-15.99	0.99743186	0.99871951	0.99871234	
16-ADULT	0.99743835	0.99870216	0.99873619	
ALL	0.99744002	0.99871716	0.99872286	

Table II – Normative EEG database sensitivities for different age groups at +/- 2 standard deviations and +/- 3 standard deviations.

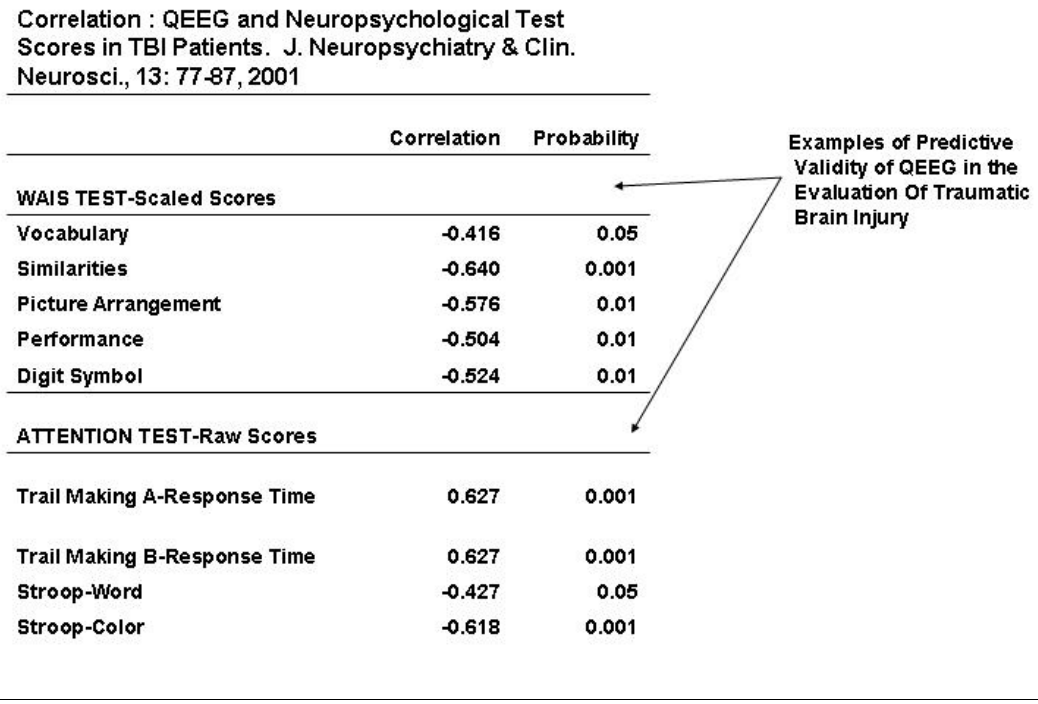
Validity concerns the relationship between what is being measured and the nature and use to which the measurement is being applied. Another way to put it is that validity is defined as the extent to which any measuring instrument measures what it is intended to measure. Just as reliability is a matter of degree, so also is validity. Hypothesis formation and hypothesis testing as emphasized in *Daubert* (2) is an important part of determining the validity of a scientific measure.

4.5 –Predictive Validity of Normative Databases

Predictive (or criterion) validity has a close relationship to hypothesis testing by subjecting the measure to a discriminant analysis or cluster analysis to some statistical analysis in order to separate a clinical sub-type from a normal reference database. Nunnally (38) gives a useful definition of predictive validity as: "when the purpose is to use an instrument to estimate some important form of

behavior that is external to the measuring instrument itself, the latter being referred to as criterion [predictive] validity." For example, science "validates" the clinical usefulness of a measure by its false positive and false negative rates and by the extent to which there are statistically significant correlations to other clinical measures and, especially, to clinical outcomes (13, 49).

An example of predictive validity of the Linked Ears qEEG normative database is shown in figure 5 in which normative database was used to discriminate



Correlation : QEEG and Neuropsychological Test Scores in TBI Patients. J. Neuropsychiatry & Clin. Neurosci., 13: 77-87, 2001

	Correlation	Probability
WAIS TEST-Scaled Scores		
Vocabulary	-0.416	0.05
Similarities	-0.640	0.001
Picture Arrangement	-0.576	0.01
Performance	-0.504	0.01
Digit Symbol	-0.524	0.01
ATTENTION TEST-Raw Scores		
Trail Making A-Response Time	0.627	0.001
Trail Making B-Response Time	0.627	0.001
Stroop-Word	-0.427	0.05
Stroop-Color	-0.618	0.001

Fig. 5 – Example of predictive and content validity by clinical correlations of QEEG with Neuropsychological test scores (39).

traumatic brain injured patients from age matched normal control subjects at a classification accuracy = 96.2% (39). Another example of predictive validity is the ability of qEEG normative values to predict cognitive functioning. Figure 6 shows correlations to Full Scale I.Q. as an example of predictive validity and content validity . A more complete analysis of the predictive validity of a

normative EEG database is shown in Table III (33, 34). In Table III the percentage of statistically significant correlations at P < .01. between qEEG normative EEG and WRAT School Achievement scores and measures of intelligence are shown. The relative effect size of the normative EEG correlations differs for different measures which is valuable information when using any normative database, not just a QEEG normative database.

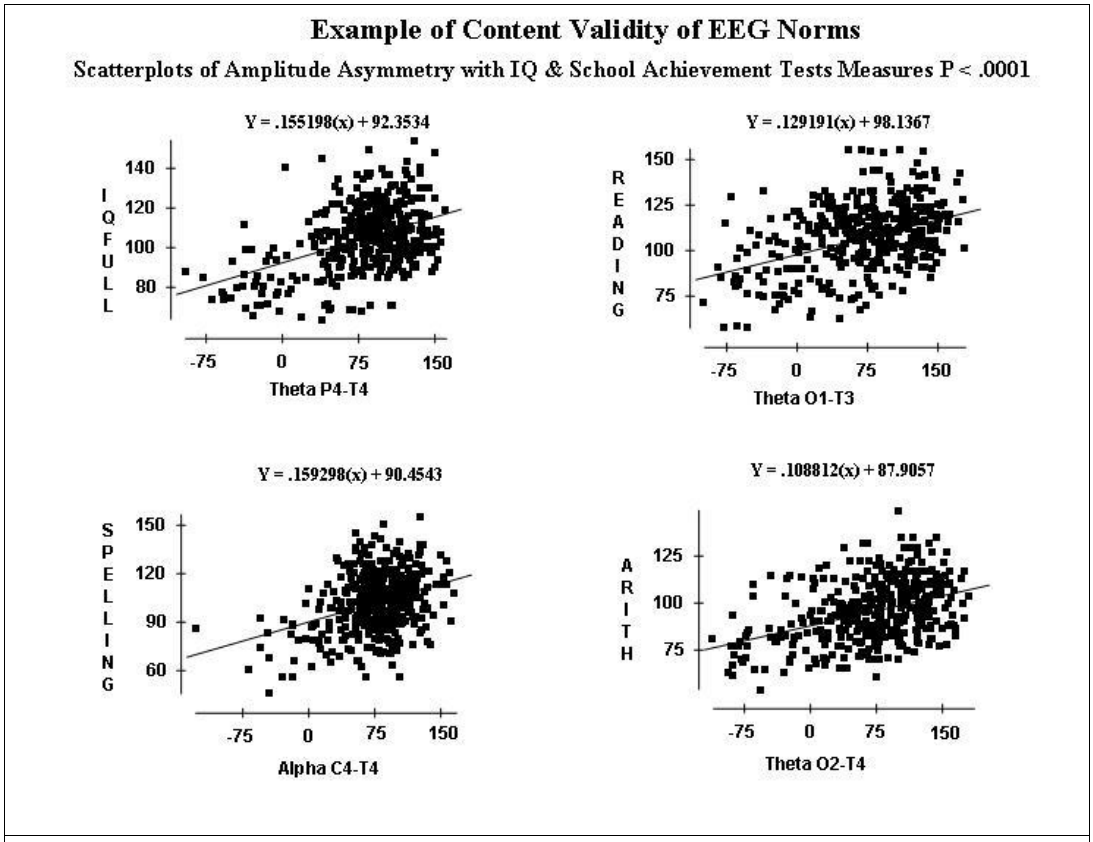


Figure 6 - Example of content validity demonstrated by statistically significant correlations between full scale I.Q. and QEEG

EFFECT SIZE P < .01: qEEG Correlations with School Achievement & IQ Measures
Percent Significant Correlations @ P < .01, N = 466

Amplitude Asymmetry						
P <= .01	READING	SPELLING	ARITH	IQFULL	IQVERB	IQPERF
DELTA	**64%**	**61%**	**55%**	**64%**	**61%**	**61%**
THETA	**78%**	**70%**	**70%**	**70%**	**67%**	**59%**
ALPHA	**63%**	**63%**	**53%**	**64%**	**63%**	**52%**
BETA	**56%**	**56%**	**34%**	**58%**	**61%**	**47%**
Coherence						
P <= .01	READING	SPELLING	ARITH	IQFULL	IQVERB	IQPERF
DELTA	**27%**	**14%**	**41%**	**38%**	**22%**	**38%**
THETA	**27%**	**6%**	**36%**	**30%**	**27%**	**23%**
ALPHA	**9%**	**6%**	**45%**	**11%**	**14%**	**5%**
BETA	**11%**	**5%**	**38%**	**22%**	**17%**	**6%**
Absolute Phase						
P <= .01	READING	SPELLING	ARITH	IQFULL	IQVERB	IQPERF
DELTA	**11%**	**8%**	**8%**	**16%**	**6%**	**17%**
THETA	**9%**	**5%**	**8%**	**13%**	**9%**	**17%**
ALPHA	**9%**	**3%**	**33%**	**14%**	**19%**	**6%**
BETA	**9%**	**5%**	**30%**	**6%**	**9%**	**3%**
Relative Power						
P <= .01	READING	SPELLING	ARITH	IQFULL	IQVERB	IQPERF
DELTA	**13%**	**0%**	**31%**	**0%**	**6%**	**0%**
THETA	**56%**	**44%**	**94%**	**6%**	**6%**	**0%**
ALPHA	**19%**	**0%**	**75%**	**0%**	**0%**	**0%**
BETA	**13%**	**6%**	**44%**	**19%**	**13%**	**13%**
Relative Power Ratios						
P <= .01	READING	SPELLING	ARITH	IQFULL	IQVERB	IQPERF
Theta/Beta	**50%**	**44%**	**63%**	**56%**	**56%**	**50%**
Theta/Alpha	**13%**	**0%**	**69%**	**0%**	**0%**	**0%**
Alpha/Beta	**50%**	**31%**	**50%**	**38%**	**38%**	**25%**
Delta/Theta	**19%**	**25%**	**56%**	**19%**	**13%**	**25%**

Table III

4.6 –Examples of Content Validity of Normative Databases

Content validity is defined by the extent to which an empirical measurement reflects a specific domain of content. For example, a test in arithmetic operations would not be content valid if the test problems focused only on addition, thus neglecting subtraction, multiplication and division. By the same token, a content-valid measure of cognitive decline following a stroke should include measures of memory capacity, attention and executive function, etc.

There are many examples of the clinical content validity of qEEG and normative databases in ADD, ADHD, Schizophrenia, Compulsive disorders, Depression, Epilepsy, TBI and a wide number of clinical groupings of patients as reviewed by Hughes and John, (13). There are 258 citations to the scientific literature in the review by Hughes and John (13) and there are approximately twenty three citations to peer reviewed journal articles in which a QEEG normal reference database was used. A year 2003 Internet search of the National Library of Medicine will give citations to many more qEEG and content validity peer reviewed studies using a reference normal group than were included in the Hughes and John (13) review.

4.7 – Non-Parametric Statistics to Measure Content Validity of a qEEG Normative Database

Non-parametric statistics such as the Binomial Probability and for small sample sizes the Poisson Probability are simple non-parametric tests that are distribution free and automatically adjust for multiple comparisons. The catch is that the non-parametric statistics must define an hypothesis by a specific statistical probability alpha level, otherwise they do not work. The Binomial Distribution is defined as $P(X) = \binom{N}{x} p^x (1-p)^{N-x}$ of successful outcomes at a specific probability, for example, P < .01 for a specific hypothesis. N = the number of Z-tests, p is the 'success rate' and 1 – p the 'failure rate' for the test of the null hypothesis, x = the number of observed Z scores at a given probability level, e.g., P < .01. For example, the null hypothesis is that by chance there will be 1 event per 64 observations at P < .01. The experiment is run and there were 5 observations at P < .01. The exact probability as computed by the Binomial Equation = P < .000421394.

Figure 7 is an example of the statistical significance of some of the clinical correlations of the EEG

BINOMIAL PROBABILITIES of Expected Significant Correlations @ P < = .01

Amplitude Asymmetry			Reading		Spelling		Arithmetic		IQFULL	
P <= .01	N	E(X)	X	P(X)	X	P(X)	X	P(X)	X	P(X)
DELTA	64	1	41	0.0000	39	0.0000	35	0.0000	41	0.0000
THETA	64	1	50	0.0000	45	0.0000	45	0.0000	45	0.0000
ALPHA	64	1	40	0.0000	40	0.0000	34	0.0000	41	0.0000
BETA	64	1	36	0.0000	36	0.0000	22	0.0000	37	0.0000

Coherence			Reading		Spelling		Arithmetic		IQFULL	
P <= .01	N	E(X)	X	P(X)	X	P(X)	X	P(X)	X	P(X)
DELTA	64	1	17	0.0000	9	0.0000	26	0.0000	24	0.0000
THETA	64	1	17	0.0000	4	0.0005	23	0.0000	19	0.0000
ALPHA	64	1	6	0.0000	4	0.0005	29	0.0000	7	0.0000
BETA	64	1	7	0.0000	3	0.0039	24	0.0000	14	0.0000

Absolute Phase			Reading		Spelling		Arithmetic		IQFULL	
P <= .01	N	E(X)	X	P(X)	X	P(X)	X	P(X)	X	P(X)
DELTA	64	1	7	0.0000	5	0.0000	5	0.0000	10	0.0000
THETA	64	1	6	0.0000	3	0.0039	5	0.0000	8	0.0000
ALPHA	64	1	6	0.0000	2	0.0265	21	0.0000	9	0.0000
BETA	64	1	6	0.0000	3	0.0039	19	0.0000	4	0.0005

Relative Power			Reading		Spelling		Arithmetic		IQFULL	
P <= .01	N	E(X)	X	P(X)	X	P(X)	X	P(X)	X	P(X)
DELTA	16	0	2	0.0005	0	0.1485	5	0.0000	0	0.1485
THETA	16	0	9	0.0000	7	0.0000	15	0.0000	1	0.0109
ALPHA	16	0	3	0.0000	0	0.1485	12	0.0000	0	0.1485
BETA	16	0	2	0.0005	1	0.0109	7	0.0000	3	0.0000

Relative Power Ratios			Reading		Spelling		Arithmetic		IQFULL	
P <= .01	N	E(X)	X	P(X)	X	P(X)	X	P(X)	X	P(X)
Theta/Beta	16	0	8	0.0000	7	0.0000	10	0.0000	9	0.0000
Theta/Alpha	16	0	2	0.0005	0	0.1485	11	0.0000	0	0.1485
Alpha/Beta	16	0	8	0.0000	5	0.0000	8	0.0000	6	0.0000
Delta/Theta	16	0	3	0.0000	4	0.0000	9	0.0000	3	0.0000

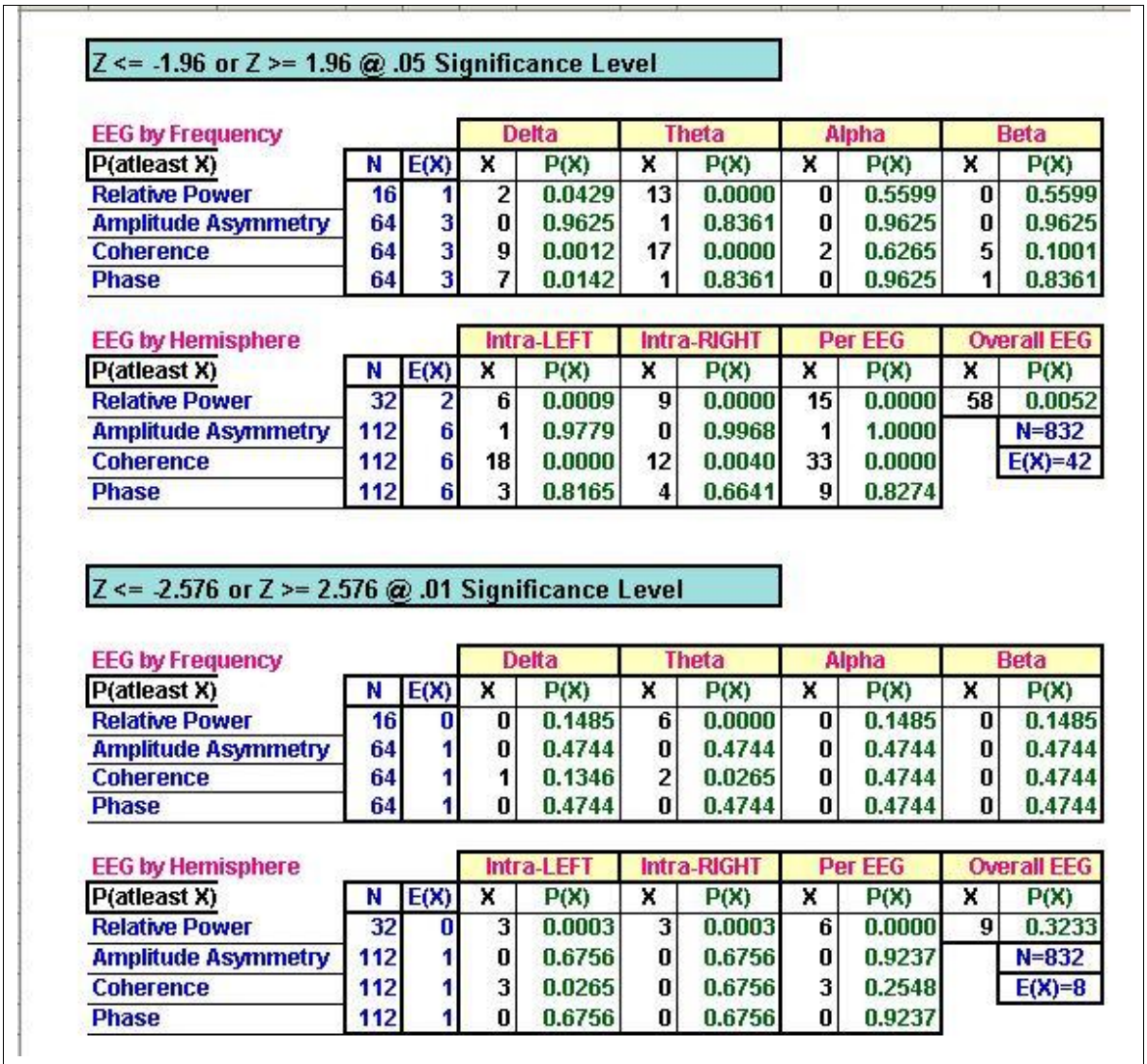
Fig. 7 – Non-parametric statistics of the content validity of an EEG normative database in which the number of multiple comparisons is accounted for.

database, i.e., Wide Range Achievement Test for Reading, Spelling, Arithmetic and Full Scale I.Q. E(X) is the expected number of correlations at $P < .01$, X = the number of observed correlations at $P < .01$ and P(X) = the Binomial Probability to reject the null-hypothesis. Table III shows the observed percentage of correlations at $P < .01$ by which the X value in figure 7 corresponds.

4.8 - Hypothesis Testing and Multiple QEEG Comparisons

The use of many t-tests or Z tests in EEG applications requires some adjustment for the total number of tests in order to accurately estimate levels of alpha or the probability of a Type I error (i.e., saying something is statistically significant when it is not). As explained by Hayes (36) Multiple comparisons refers to multiple group comparisons and not to the adjustment of the total number of t-tests or Z-tests, where as, non-parametric statistics is one of the best methods to adjust for both Type I and Type II error rates.

In order to use non-parametric statistics with an EEG normative database one must begin with a Null Hypothesis, e.g., null-hypothesis is that 50% of the Z scores are negative or all Z scores = 0, or only the left hemisphere has positive Z scores, etc. Once one or more null-Hypothesis are generated then a simple non-parametric statistic by which one may reject the null-hypothesis can be constructed called the Binomial Distribution and for smaller sample sizes the Poisson Distribution which approximates the Binomial (Hayes, 36). The Binomial Distribution is defined as $P(X) = \binom{N}{x} p^x (1-p)^{N-x}$ of successful outcomes at a specific probability, for example, P < .05 for a specific hypothesis. N = the number of Z-tests, p is the 'yes' and q the 'no' test of the null hypothesis, x = the number of observed Z scores at a given probability value, e.g., P < .05. Figure 8 shows an example of the use of the Binomial Probability Distribution to determine the alpha level for the complex demodulation norms. The number of Z tests is represented as 'N', E(X) = the number expected by chance alone at P < .05 (Top of Figure 8) or at P < .01 (Bottom of Figure 8), X = the number of successful Z tests observed and P(X) = the Binomial Probability.



Z <= -1.96 or Z >= 1.96 @ .05 Significance Level

EEG by Frequency			Delta		Theta		Alpha		Beta	
P(atleast X)	N	E(X)	X	P(X)	X	P(X)	X	P(X)	X	P(X)
Relative Power	16	1	2	0.0429	13	0.0000	0	0.5599	0	0.5599
Amplitude Asymmetry	64	3	0	0.9625	1	0.8361	0	0.9625	0	0.9625
Coherence	64	3	9	0.0012	17	0.0000	2	0.6265	5	0.1001
Phase	64	3	7	0.0142	1	0.8361	0	0.9625	1	0.8361

EEG by Hemisphere			Intra-LEFT		Intra-RIGHT		Per EEG		Overall EEG	
P(atleast X)	N	E(X)	X	P(X)	X	P(X)	X	P(X)	X	P(X)
Relative Power	32	2	6	0.0009	9	0.0000	15	0.0000	58	0.0052
Amplitude Asymmetry	112	6	1	0.9779	0	0.9968	1	1.0000		N=832
Coherence	112	6	18	0.0000	12	0.0040	33	0.0000		E(X)=42
Phase	112	6	3	0.8165	4	0.6641	9	0.8274		

Z <= -2.576 or Z >= 2.576 @ .01 Significance Level

EEG by Frequency			Delta		Theta		Alpha		Beta	
P(atleast X)	N	E(X)	X	P(X)	X	P(X)	X	P(X)	X	P(X)
Relative Power	16	0	0	0.1485	6	0.0000	0	0.1485	0	0.1485
Amplitude Asymmetry	64	1	0	0.4744	0	0.4744	0	0.4744	0	0.4744
Coherence	64	1	1	0.1346	2	0.0265	0	0.4744	0	0.4744
Phase	64	1	0	0.4744	0	0.4744	0	0.4744	0	0.4744

EEG by Hemisphere			Intra-LEFT		Intra-RIGHT		Per EEG		Overall EEG	
P(atleast X)	N	E(X)	X	P(X)	X	P(X)	X	P(X)	X	P(X)
Relative Power	32	0	3	0.0003	3	0.0003	6	0.0000	9	0.3233
Amplitude Asymmetry	112	1	0	0.6756	0	0.6756	0	0.9237		N=832
Coherence	112	1	3	0.0265	0	0.6756	3	0.2548		E(X)=8
Phase	112	1	0	0.6756	0	0.6756	0	0.9237		

Fig. 8 - Non-parametric statistical comparison of a single individual's EEG values to a QEEG normative database.

Figure 8 is only one example of how non-parametric statistics are used to test hypotheses, to minimize eliminate multiple comparisons and to test specific hypotheses as per *Daubert* factors 1 and 2.

5.0 - Suggestion for Expert Witnesses: Document QEEG Hypotheses of Predictive Validity

Predictive validity is sometimes referred to as "criterion validity" and has a close relationship to hypothesis testing by subjecting the measure to an independent test of its ability to predict clinical measures such as severity of

injury or intelligence, attention, executive function, etc. Nunnally (38) gives a useful definition of predictive validity as: "when the purpose is to use an instrument to estimate some important form of behavior that is external to the measuring instrument itself, the latter being referred to as criterion-validity." For example, one "validates" a written driver's license test by hypothesizing that it accurately predicts how well some group of persons can operate an automobile. If the driving test fails to predict driving competence, then the test must be rejected or replaced. In the case of traumatic brain injury (TBI) one "validates" the QEEG by showing that it accurately predicts severity of TBI as measured by Hospital admission scores such as the Glasgow Coma Score (GCS) or length of coma or in other independent tests such as neuropsychological tests, etc. (13, 39).

5.1 – False Positive and False Negative Error Rates of QEEG: Example of Content Validity in Traumatic Brain Injury

Peer reviewed scientific publications of 608 mild TBI patients compared to 108 age matched normal subjects demonstrated, in independent cross-validations an average false positive rate approximately 5% and an average false negative rate of approximately = 10% to 15% (40). Similar levels of sensitivity and specificity were reported in a series of independent and replicated QEEG studies of TBI in which sensitivity = 95.45% and specificity = 97.44% for the detection of a pattern consistent with traumatic brain injury as a causal agent (39, 46). Obtaining a content-valid measure of any phenomena involves at least three interrelated steps: 1- one must be able to specify the full domain of content that is relevant, 2- one must be able to identify the selection of relevant measures from the larger universe of possible measures with the understanding that over sampling is usually necessary and 3- one must be able to test the content validity of the measuring instrument and/or be able to cite the peer reviewed literature in which the content-validity of the QEEG had been tested. As stated by Cronback (37) "One validates, not a test, but an *interpretation of data arising from a specified procedure*". This distinction is crucial because it is quite possible for a

measuring instrument to be relatively valid for measuring one kind of phenomenon but entirely invalid for assessing other phenomena.

QEEG involves the measurement of a relatively large number of electrical processes some of which may be affected by a traumatic brain injury (TBI). For example, animal studies and imaging studies in humans have demonstrated that maximal damage to the brain following TBI occurs at the interface between the brain and the skull bone (41, 42). Another primary and common injury to the brain due to TBI are "shear" forces in which rapid acceleration/deceleration results in different brain parts moving at different rates, for example, the gray matter moves faster and further than the white matter thus stretching axonal fibers, etc. (41). Thus, a content valid QEEG measure of TBI should be capable of measuring electrical activity in frontal and temporal lobes where the brain-to-skull forces are greatest. Similarly, a content valid QEEG test of TBI must be capable of measuring EEG phase and EEG coherence which reflect the axonal conduction velocities and long distance cortical communication linkages (44, 45, 47, 48).

5.2 - Suggestions for Expert Witnesses: QEEG Construct Validity

Construct validity is concerned with the validity of empirical measures and hypothesis testing of theoretical concepts. As Carmines and Zeller (16) state: "Construct validity is concerned with the extent to which a particular measure relates to other measures consistent with theoretically derived hypotheses concerning the concepts that are being measured". Construct validity typically involves three steps: 1- the theoretical relationship between the concepts themselves must be specified and testable hypotheses stated, 2- the empirical relationship between the measures of the concepts must be examined and, 3- the empirical evidence must be interpreted in terms of how it affirms, rejects or clarifies the construct validity of the particular measure.

For example, in QEEG measures of traumatic brain injury one hypothesis is that rapid acceleration/deceleration contuses (bruises) brain tissue especially

where the brain sits on the bony skull vault (41, 42, 43), another theory is that damage to neuronal membranes will results in reduced ionic flows and reduced amplitude of the EEG and high frequencies and a shift in frequency toward the theta and delta frequencies (lower frequency ranges). These two theoretical hypotheses regarding which QEEG measures would be expected to change following TBI have been tested and confirmed in the peer reviewed scientific literature (45, 47, 48, 50 - 52).

Figure 9 is an example of construct validity of the QEEG in the measurement of TBI in which correlations of MRI were used to test the null hypothesis = 0, about damage to the average concentration of ionic channels in a volume of cortex that produces EEG (45, 47, 48).

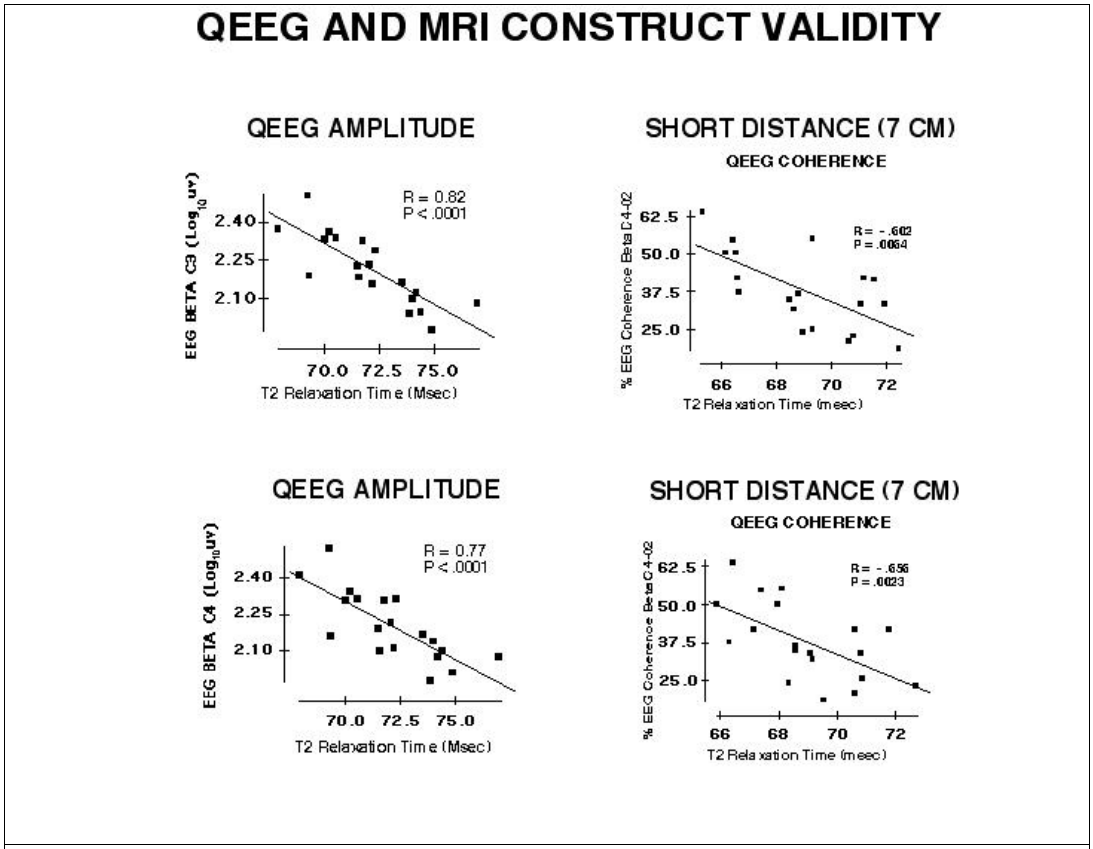


Fig. 9. An example of construct validity of the QEEG to correlate with the MRI in the estimate of traumatic brain injury (adapted from 45, 47).

In fig. 9, construct validity of QEEG was tested by examining the hypothesized relationship between the integrity of gray matter membranes using the MRI and

the amplitude and coherence of the EEG. The hypothesis predicted reduced connectivity and a decline in amplitude of the EEG related to reduced integrity of neural membranes. The results of the construct validity tests of the QEEG in TBI were born out as valid as reported in peer reviewed publications (45, 47, 48). These same studies also tested content validity by correlating the independent MRI measures with selected QEEG measures and finally, predictive validity was also tested by correlations with neuropsychological test scores which co-varied with both the QEEG and the MRI in a predictable manner.

6.0 – Acceptance of QEEG in Court Rooms

According to *Daubert* general acceptance of any technical or scientific method is linked to the peer reviewed literature. Therefore, an attorney should ask any expert witness as to his/her familiarity with the peer reviewed scientific research in support of QEEG and TBI. The peer reviewed literature is available in libraries and over the internet, for example, by using the National Library of Medicine's search engine and other library searches. The expert must be familiar with the peer reviewed literature, and preferably, also by publishing peer reviewed papers him/her self and having first hand experience (this is what makes an expert and expert). I would advise an attorney to search the National Library of Medicine website website (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi) using the key words "QEEG and whatever neurological or psychological disorder is of interest" and then presenting your expert with a printed listing as starters and asking the expert witness if he has read or is aware of the articles publicly available at the National Library of Medicine. If the expert witness is not familiar with the literature then do not use him as an expert witness because he is not an expert. Test the experience and knowledge of the expert witness and the rebuttal witnesses in all of your depositions, hearings and trials, because we all know that there is opinion and then there is science and the National Library of Medicine listings of journal articles regarding the clinical applications of QEEG bear on the

extent of acceptance in the scientific and clinical community as established in *Frye* and *Daubert*.

A qualified expert witness should be familiar with the peer reviewed scientific literature that establishes the predictive, content and construct validity of the QEEG in predicting GCS and neuropsychological function and brain dysfunction following TBI and be able to introduce exhibits of published papers and/or the tables and figures as evidence at trial if necessary (this is what an attorney should seek from his expert). A few of examples of additional peer reviewed studies of QEEG and TBI, beyond those already cited are (42 – 45).

7.0 – The American Academy of Neurology 1997 Position on QEEG and Medical-Legal Evidence Fails to Pass the *Daubert* Standards for Admission

The American Academy of Neurology position paper should be praised for much of the body of the text and it contained many excellent contributions and evaluations about the clinical use of QEEG in selected areas. However, the AAN paper was not as consistently excellent when it came to the medical-legal aspects of medical science and clinical medical records such as QEEG and the AAN needs to revisit the issue of Medical-Legal recommendations. Following the 1997 ANN non-scientific "position paper" a series of peer reviewed rebuttal articles all addressing the lack of citations to the scientific literature were published (13 - 15). The consistent criticisms of the AAN (1) paper in the peer reviewed literature were its lack of scientific foundations (13 - 15), which significantly weights against the ANN's 1997 "proclamation" (1). The AAN position paper (1) failed to meet the *Daubert* standards of acceptable science in regard to QEEG because it did not cite the peer reviewed literature regarding existing reliability and/or validity studies (19 - 26), nor did it cite peer reviewed literature rebutting the literature that QEEG is unreliable or not valid in the measurement of well established neurological and psychological disorders (13). The American Academy of Neurology's failure to cite the numerous peer reviewed publications in support of QEEG's validity and reliability was

compounded by it's reliance on unknown and "anonymous" sources ((1) p. 283). As a consequence, the ANN's position paper's own words were denied admission in Circuit Court No. 1, Austin, Texas in 1999 (53). In the Austin 1999 trial, the Judge correctly admitted QEEG evidence in a traumatic brain injury case and he correctly denied admission of the American Academy of Neurology's opinion about QEEG and traumatic brain injury (15). In essence, the 1999 Texas State court held that the AAN's statements about QEEG failed to meet acceptable standards of science.

More pertinent is the AAN's general misapplication of the standards of science as expressed in the section on "Medical-legal abuse." of QEEG (1) (p. 284) which should be directed more to poorly trained and unqualified experts than to the technology of QEEG itself. As mentioned previously, AAN's general position on alleged "Medical-legal Abuse" in the court room is a contradiction of the AAN's own endorsements of QEEG as an accepted clinical methodology in the QEEG of dementia, QEEG of stroke, QEEG of epilepsy and QEEG in intraoperative monitoring (1, p. 280 - 282). This is another reason that the AAN is encouraged to revisit these issues with a goal to produce a revision or a new paper that retains the basic standards in the 1997 paper but interprets them much more in line with the standards of science espoused in *Daubert* (2) and the subsequent standards in *Kuhmo* (3) and *General Electric* (16).

8.0- Advice to Attorney's

Within the legal profession there is confusion about the meaning of the language of *Daubert* or confusion by judges about what is meant by the standards "scientific knowledge" or "technical knowledge" or "Specialized knowledge". The expert witness has the responsibility to educate and inform the attorney and the judge and the jury. This is the crucial and traditional role of an expert and to the extent an individual expert witness can not do this, then they should not be retained by the attorney. Attorneys should demand that their expert witnesses present the peer reviewed literature to them in writing such as in abstracts or

citations to the literature which the attorney can study. The expert must explain the science involved in cases similar to the attorney's case, and then after reviewing the facts produced by the expert the attorney asks for the opinion of the expert as to the meaning of the facts and the science in his/her client's case. The attorney must take the time to discuss by telephone or meet with the expert witness the entire case and the witness needs to respond quickly and scientifically to the attorney's requests. The given expert's opinion may or may not meet the facts and the law in a given case for a variety of reasons and the attorney has a legal obligation to keep all communications as privileged.

To iterate a note of caution, if the expert fails to satisfactorily and reasonably educate the attorney about the scientific literature or the expert has not personally read the scientific literature then do not retain the alleged "expert". Attorney's must recognize that large CVs, M.D. degrees and Ph.D. degrees and multiple board certifications and multiple pages of credentials in a curriculum vitae mean nothing if the expert can not educate the attorney and cite the scientific literature and be articulate enough to educate as to the scientific facts involved in the client's case. Ultimately, it is the attorney who educates the judge and the jury about the science with the help of experts, testimony and exhibits.

Appellate reversal is more likely when the court record showed abuse of discretion as to the Supreme Court's *Daubert* rulings of admissibility using exhibits and hearing testimony in his/her appeal and establishing the connection to the FOUR Daubert factors presented to a judge in a hearing who then ruled against admission of QEEG at trial.

As a final emphasis and reminder, Justice Blackmum's earlier quotation in *Daubert* is worth repeating: ":

> "We conclude by briefly addressing what appear to be two underlying concerns.... Respondent expresses apprehension that abandonment of "general acceptance"... will result in a "free-for-all" in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions. In this regard respondent seems to us to be overly pessimistic about the capabilities of the jury, and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful

instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." (2).

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