EEG spectral fingerprinting as a new method of safeguarding data integrity in multicenter trials

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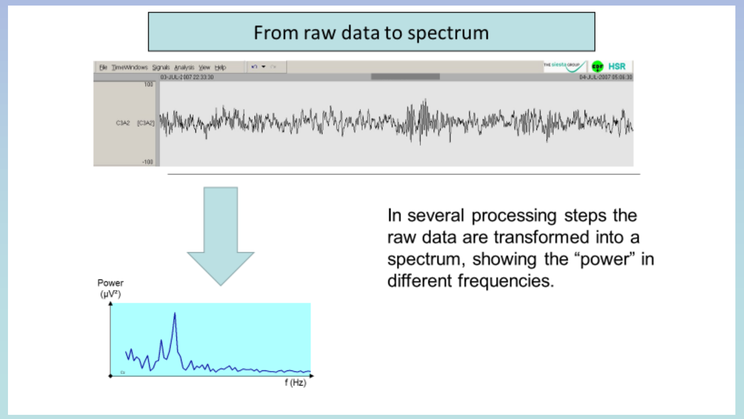
OBJECTIVES AND AIMS

Phase II and III CNS clinical trials involving the polysomnographic measurement of sleep (PSG) are usually multi-centric, involving many (up to 100) different sites. Visual scoring and computerized analysis of the acquired raw data is commonly performed at a central scoring center. This scenario implies that PSG/EEG data need to be transferred to the central scorer.

However, up to now there is no proof that the data sent indeed matches the correct subject. The data flow from site to data center involves several (sometimes manual) steps and, thus, is potentially prone to accidental or even deliberate confusion or duplication of data. Despite the fact that this kind of error is rare, they do occur and might spoil the statistical results of a trial.

This paper proposes a new tool for risk management, taking advantage of the fact that the human sleep EEG is characteristic for an individual comparable to a fingerprint.



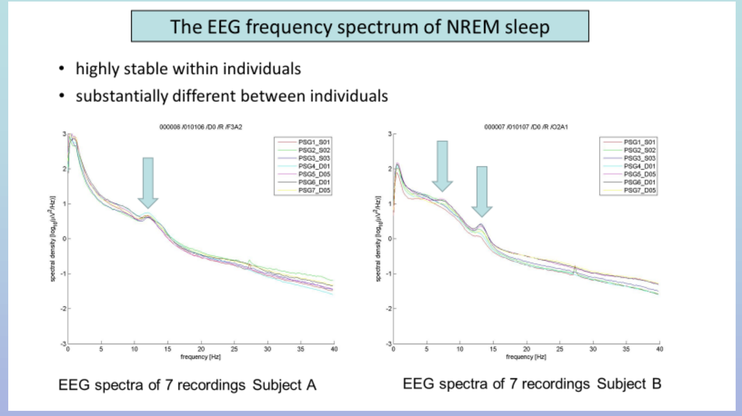


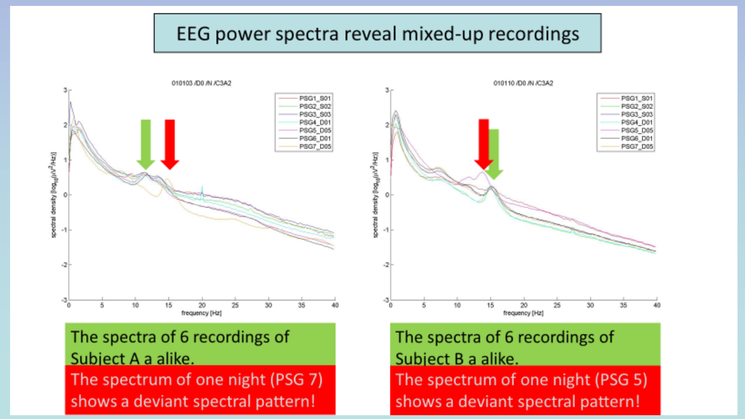
Fig.1

DESIGN

It has been shown that the frequency spectrum of the NREM sleep EEG is highly stable within individuals but substantially different between individuals (Fig.1). Out of 174 PSG recordings, 155 (89%) could be correctly identified from the spectrum alone (Lewandowski et al. 2013). The method is equally robust to experimental challenges even as massive as total sleep deprivation. It is genetically determined and has been shown to be one of the most heritable traits in humans.

RESULTS

Based on these findings, in our solution the spectral signature of each PSG recording received is matched to recordings from the same subject acquired at other time points. Any mismatch is revealed instantly (Fig.2). Likewise, any duplicate data would be disclosed, even when time stamps are manipulated. This is not possible with any checksum based algorithm. Moreover, the presented solution has the advantage of detecting incorrect EEG settings, mixed-up electrodes or recordings contaminated by abundant artifacts.



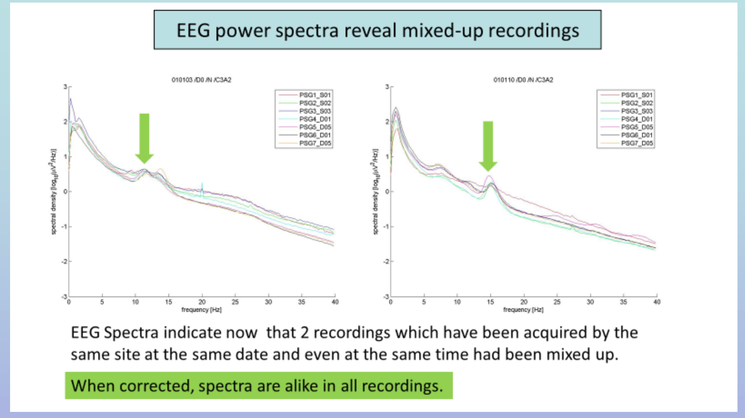


Fig.2

CONCLUSION

The presented method allows centralized monitoring to detect discrepancies in data immediately and thus is able to take corrective actions in real time.

Reference: Lewandowski A, Rosipal R, Dorffner G. On the Individuality of Sleep EEG Spectra. Journal of Psychophysiology. 2013 Jul 22;27(3):105-112.