TETRAGRAPH

Clinical Summary

Train-of-four ratio, counts and post-tetanic counts with the TetraGraph electromyograph in comparison with mechanomyography[1]

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Background:

Quantitative train-of-four (TOF) monitoring is crucial to preventing residual paralysis and ensuring patient safety during anesthesia. Traditional mechanomyography (MMG) is the historical gold standard for neuromuscular monitoring but is cumbersome and unavailable for clinical use. The TetraGraph® electromyography (EMG) monitor, a portable and user-friendly device, was compared against a custom-designed validated MMG device to compare its accuracy and reliability across all phases of neuromuscular block (onset, depth and reversal), including post-tetanic count (PTC) measurements of deep block.

Objective:

To assess the accuracy and precision of the TetraGraph® EMG system in comparison to MMG, focusing on train-of-four (TOF) ratios, TOF counts, and PTC measurements.

Methods:

A total of 26 patients undergoing elective surgery were monitored simultaneously with both the TetraGraph® EMG and a validated MMG device. Over 685 paired recordings were analyzed, including TOF ratios, TOF counts, and PTC measurements. Bland-Altman analysis was used to assess the bias between the two modalities.

Key Findings:

Highest Clinical Accuracy Obtained:
The TetraGraph® EMG system demonstrated a mean difference (bias) of -2.1% when compared to the MMG reference standard, representing the highest accuracy obtained in a validation study to date.

Validated at All Levels of Block:
95% of PTC measurements (deep block) were within two counts of MMG, 96% of TOF count measurements (moderate block) were within two counts of MMG, and 56% and 23%, respectively, were identical, showcasing the TetraGraph's precision at deep and moderate levels of block. For recovery (minimal block), the TetraGraph and MMG ratios were identical (92%±2.2 and 92%±5.7, respectively).

Establishment of EMG as the New Standard:
The ease of use and accuracy across all phases of neuromuscular block, including onset, maintenance, and reversal, validate EMG and the TetraGraph as the new clinical standard in quantitative TOF monitoring.

Conclusion:

TetraGraph® EMG has been clinically validated as more accurate and consistent—at all levels of block including deep—than MMG, with strong correlations ($r > 0.9$) across TOF ratios, TOF counts, and PTC measurements. Its portable design, accuracy at all levels of block, and simplicity of use make it an ideal tool for neuromuscular monitoring in clinical settings.

Clinical Relevance:

TetraGraph® EMG delivers reliable monitoring at all depths of neuromuscular block—including PTC—making it indispensable for improving patient outcomes and aligning with guidelines from the American (ASA) and European (ESAIC) societies.

SENZIME

EMG Devices Comparison:

Accuracy to reference for commercially available EMG neuromuscular monitoring devices*[1-3]

Graph:

Accuracy to reference for commercially available EMG neuromuscular monitoring devices*[1-3]

***Calculated as 1-Bias vs. MMG**
The TetraGraph was shown to achieve the highest accuracy in a validation study, with the least likelihood of over-reading baseline train-of-four ratio measurements.

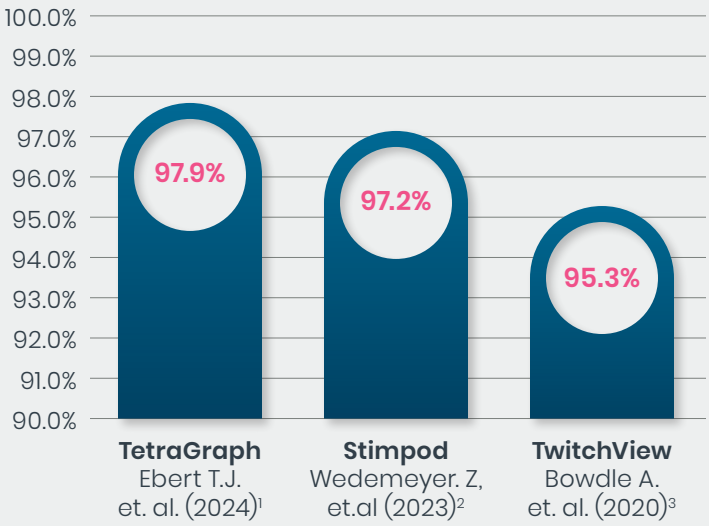

Table:

Clinical Validation Studies Comparison Overview

Device	Bias	Key Findings	Conclusion
Stimpod (Xavant)[2]	2.8%	• 1,088 data pairs from 23 patients. • Agreement for TOF count: kappa = 0.44; for PTC: kappa = 0.80 (substantial).	Stimpod accurate, suitable for clinical use.
TwitchView (prototype device; Blink DC)[3]	4.7%	• 2,011 pairs from 43 subjects. • Substantial agreement (kappa = 0.67). • Acc. often underestimated TOF counts.	TwitchView reliable for TOF counts. AMG underestimates.
TetraGraph (Senzime)[1]	-2.1%	• 685 paired responses from 26 patients. • Close agreement with MMG (r > 0.9). • PTC differences within 2 counts (96%).	TetraGraph aligns closely with MMG, with substantial agreement, which supports its clinical use in all depths of neuromuscular block

The TwitchView's validation study has several key limitations:

- The TwitchView validation study was conducted on a pre-market prototype device, not the fully commercialized version, which may not reflect the final product's performance or accuracy; in contrast, the TetraGraph was validated using the fully commercialized device, ensuring clinically relevant and reliable results.[1, 3]
- TwitchView's validation focused solely on train-of-four (TOF) ratios and TOF counts and did not include post-tetanic counts (PTC), making it valid only for shallow and moderate block, while TetraGraph is also validated for deep block.[3]
- The TwitchView measurements were not compared with MMG for 10 minutes following administration of NMBAs, "in order to avoid periods when the extent of neuromuscular blockade was changing very rapidly." This means that there are few comparisons between devices during the clinically relevant periods of rapid neuromuscular block onset and recovery.[3]

References:

1. Ebert TJ, Vogt J, Kaur R, Iqbal Z, Peters D, Cummings CE, Stekiel TA. Train-of-four ratio, counts and post-tetanic counts with the TetraGraph electromyograph in comparison with mechanomyography.. *Journal of Clinical Monitoring and Computing*, August 2024.
2. Wedemeyer, Z., et al. "Comparative Performance of Stimpod Electromyography with Mechanomyography for Quantitative Neuromuscular Blockade Monitoring." *Journal of Clinical Monitoring and Computing*, vol. 38, 2023, pp. 205-212. https://doi.org/10.1007/s10877-023-01087-1.
3. Bowdle A, Bussey L, Michaelsen K, Jelacic S, Nair B, Togashi K, Hulvershorn J. "A Comparison of a Prototype Electromyograph vs. a Mechanomyograph and an Acceleromyograph for Assessment of Neuromuscular Blockade." *Anaesthesia*, vol. 75, 2020, pp. 187-195. https://doi.org/10.1111/anae.14872.

Access additional clinical evidence as well as learn more about quantitative train-of-four monitoring and the benefits of EMG technology.

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