DEVELOPMENT AND VALIDATION OF AN EARLY-WARNING-SYSTEM FOR RECURRENT LARYNGEAL NERVE PROTECTION IN THYROID SURGERY

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Background/Purpose: Despite Intraoperative nerve-localisation through visualization and electrical stimulation, recurrent-laryngeal-nerve-palsy (RLN-palsy) is still a relevant complication in thyroid surgery, especially in complex procedures e.g. thyroid-cancer surgery. Transsection and clipping of the nerve has been reduced through these methods, but indirect nerve trauma by physical stress e.g. pressure and strain cannot be safely prevented. Electromyography(EMG)-based continuous-intraoperative-neuromonitoring (CIONM) in thyroid surgery has shown potential to overcome these limitations. However, currently available CIONM-systems comprise no reliable automatic signal-analysis and intuitive, non-distracting information display to the surgeon.
Our goal was to develop an early-warning-system for intraoperative nerve-trauma.

Methods:
1. Analysis of CIONM-data recorded during thyroid surgery. Identification of empirical signal-characteristics for classification and evaluation of motor-potentials (retrosp. clinical study, n=67).
2. Experimental assessment of the correlation between physical stress and EMG-changes (in-vivo epxeriment, n=3)
3. Evaluation of methods for auditory display of CIONM-data (volunteer-study, n=32).
4. Implementation&validation of the results in a realtime-system.
5. Intraoperative proof-of-concept (pilot-study, n=12).

Results: Empirical automatic classification of EMG signals provided 97,1% sensitivity and 98,1% specificity. Changes in EMG amplitude and latency highly correlated to physical nerve strain even before nerve trauma was induced ($p>0.00001$, FIg. 2a+b).
Synthetic auditory display allowed for 50% earlier detection of EMG-changes than currently available analog EMG display (Fig. 3).
The realtime system SAFE (**s**ignal-**a**nalysis-**a**nd-**fe**edback) correctly detected 99,1% of intraoperative motor-potentials. In 5/12 cases, the surgical strategy was altered based on the detection of the SAFE early-warning system.

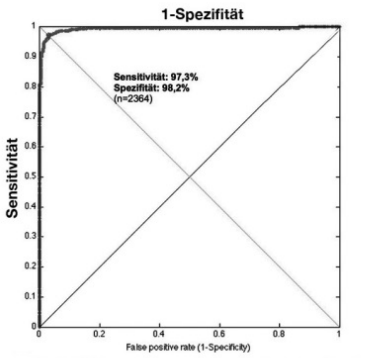

Fig 1: ROC-curve for motor-potential classification

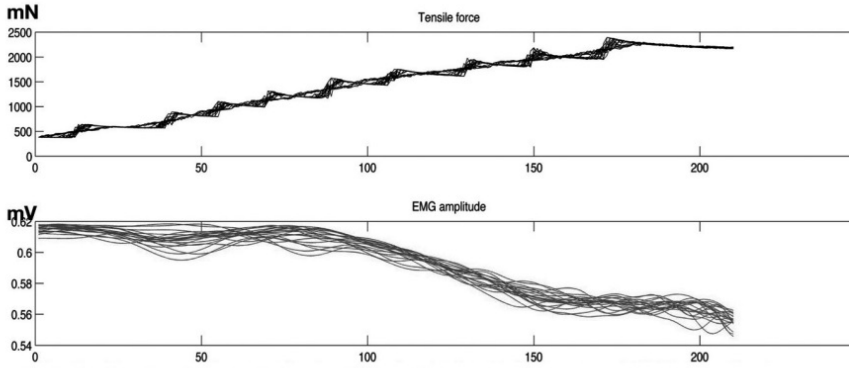

Fig. 2a: Relationship between tensile force and EMG amplitude

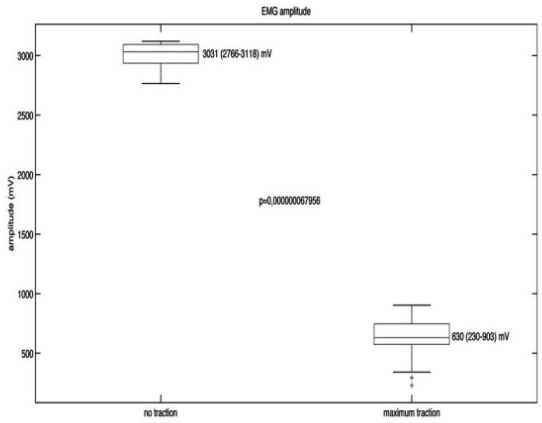

Fig. 2b EMG amplitude with and without tensile force on the RLN

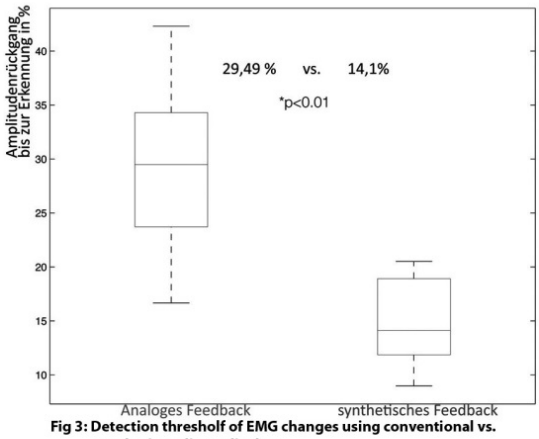

Fig 3: Detection thresholf of EMG changes using conventional vs. synthetic auditory display

Discussion & Conclusion: Fully-automatic EMG analysis in CIONM is feasible in realtime. Changes in motor-nerve function preceding indirect nerve-damage can be reliably displayed to the surgeon without distraction from the procedure.