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Development and validation of methods for automatic analysis and realtime monitoring of motor nerve function during surgery

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Intraoperative motor nerve injury is a notorious complication in surgery. In thyroid surgery, recurrent laryngeal nerve palsy can result in vocal chord dysfunction with severe clinical implications for the patient. In the last century, the incidence of surgical nerve injury by direct trauma e.g. transection, ligation and clipping has been gradually reduced through nerve visualization and Intraoperative Neuromonitoring (IONM). However, indirect nerve injury by physical stress such as pressure and strain cannot be prevented so far. Continuous intraoperative neuromonitoring (CIONM) in thyroid surgery has shown potential to overcome these limitations. However, the technology used in CIONM is insufficient. Currently available systems comprise neither reliable automatic signal analysis nor intuitive, non-distracting information display to the surgeon. Analog EMG data representation through auditory display has been available, but has remained unchanged for decades despite poor reliability and weak predictive power regarding relevant clinical outcomes.
The aim of this thesis was to identify the requirements for clinically useful CIONM, to develop a methodology for automatic EMG analysis and auditory data display and to implement theses methods in a fully functional prototype system.
The methodology of the in-vivo experiments, bench-tests and user tests, the software algorithms for EMG analysis, the validation methodology and the hardware and software development of the realtime EMG analysis and display system were created by the author alone in the scope of this thesis.
The methodical approach was subdivided into 5 parts.

- Experimental assessment of the correlation between physical stress and EMG-changes (in-vivo experiment, n=2)
- Retrospective analysis of CIONM-data recorded during thyroid surgery for the identification of empirical signal characteristics for classification and evaluation of motor-potentials (n=67).
- Evaluation of methods for auditory display of CIONM-data in a volunteer-study (n=11).
- Implementation of the results in a realtime-system.
- Clinical proof-of-concept

The correlation of EMG amplitude and latency to physical nerve strain was demonstrated in the in-vivo setting.
753401 single motor potentials were extracted from 67 surgeries and retrospectively analyzed, resulting in the development of a method for empirical automatic classification of EMG signals. Validation of the method yielded 97,2% sensitivity and 97,9% specificity.
The threshold for the detection of EMG-changes by volunteer surgeons / physicians was reduced by 50% using the author’s synthetic auditory feedback system compared to state-of-the-art EMG audio display.

The final result of this thesis is a realtime system that provides highly sensitive and specific automatic monitoring of parameters predicting nerve-trauma during thyroid surgery. The feasibility of realtime intraoperative automatic neuromonitoring signal analysis and information display during thyroid surgery was demonstrated in a clinical proof-of-concept. The realtime system ‘SAFE’ (*Signal Analysis and Feedback Electromyography*) correctly detected 98,3% of motor potentials during thyroid surgery.

The presented research shows that a new approach for CIONM data analysis and display is required and feasible. The findings of this thesis shall help to provide a foundation for the reliable detection and eventual prevention of motor nerve injury during surgery.