

Tissue interrogation using mass spectrometry based diagnostic techniques

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IMPACT

IMPACT: Implementation into clinic

At the present time, the REIMS source and the associated ancillary equipment are still for research applications only. Currently, all generated data is for the purpose of research and will not be used to provide a diagnosis, since the REIMS source has not yet been CE marked in accordance to the EU medical device directive. Therefore, application for CE marking would be required for REIMS to be marketed as a medical device. The analyses of surgical smoke represents a challenge, since it does neither match the classic *in vivo* medical tests (such as drug administration and isotope based imaging) or the *ex vivo* medical tests.

However, some substantial steps remain before the implementation of REIMS into the operation theatre. An expected obstacle might be the additional acoustic noise generated by the mass spectrometer pumps in the OR. Operating rooms are often noisy due to the high capacity air conditioning systems, monitors and alarms. Furthermore, due to the outflow of the mass spectrometer and the venturi pump, a disruption of the room airflow responsible for infection control during surgery might occur.

In a future step, this technique will be moved from the laboratory into the operating room for intraoperative validation of the results. Air and nitrogen gas supply, needed to operate the QTOF, are available in all operation theatres. The full equipment is transportable and can therefore easily be moved between the different operating rooms. The system consists of an analysis device (iKnife connected to a mass spectrometer), a computer with mass spectrometry analysis software to automatically analyse the REIMS spectra and an indication screen for the neurosurgeon. This screen shows a fast and clear indication of the type, grade and/or cell percentage of the tumour. The depicted information is based on previously built databases and PCA/LDA analyses. Importantly, in the operating room, it is expected that a monitor will directly provide the surgeon with a fast and clear diagnostic result, without the need for any mass spectrometric training.