**Best practice: surgeon driven application in pelvic operations**

From Neurophysiological Scientific Research towards Applied Technology

**Abstract:** In applied biomedical engineering and medical industry the transfer of established technology towards customers’ needs is essential for successful development and therefore business opportunities. In chronological order, we can show the transfer of scientific results of neurophysiological research into an existing neuromonitoring system and product which can be used by non-experts in medical technology in the operating room environment. All neurophysiology functions were realized in an intuitive graphical user interface. To stimulate the autonomous nerves, a specialized parameter paradigm was used, different from motor nerve stimulation. In the background, a complex signal processing algorithm recorded smooth muscle and bladder manometry data in synchronized time and automatically detected neurophysiological signals. The acquired data was then presented in real-time. With this effort a complex scientific task could be simplified to a Yes/No statement to the end-user. Beside all the reduction of complexity, the scientific challenge was still obtained, as raw-data is still possible to be recorded.

**Keywords:** electromyography; operating room; pelvic intraoperative neuromonitoring; pressure sensing; smooth muscle; surgeon.

**1 Introduction**

Intraoperative Neurophysiological Neuromonitoring (IONM) is a tool for surgeons, neurologists and neurophysiologists to map and continuously supervise nerve functions during surgical interventions. To perform this procedure, a technical device is placed in the operation room (OR) and is operated by trained staff.

IONM during the standard procedure of many surgical interventions is well established; e.g. in neurosurgical, spine or orthopaedic surgeries, the central nervous system, either the brain or the spine, can be endangered. Therefore, IONM is used and established as a standard method with complex setups. In general surgery and ear-nose-and-throat surgery, monitoring is also a fact – standard setups to monitor specific nerves are well established [1].

However, for the pelvic region, a monitoring method for the autonomous nerves was lacking for a long time. One of the challenges lied within finding the possibilities of recording the responses of the autonomous nervous system which could be monitored to perform IONM in the pelvic region. But the need for a method was clearly required due to the postoperative urogenital and anorectal functional disorders. They are accounted to the special complications after surgeries in the pelvic region [2].

A nerve-preserving operation technique could lead to an increased postoperative quality of life. To achieve this goal, a suitable method for identification and sparing of the nerves at risk had to be developed. Many paradigms were comparable to existing IONM methods but needed adjustment in their details. As a result, in recent years, neuromonitoring in the pelvic region, especially during total mesorectal excision (TME) was introduced in Germany as a new monitoring method [3] and was well received. This is now known as pelvic intraoperative (neurophysiologic) neuromonitoring pIONM® or short pIOM®.
We describe the adaptations towards today’s needs from the initial development in the following chapters.

2 Surgeon’s requirements

One major requirement in the OR is the clear representation of recorded data from the device. Regardless of the data complexity, the representation has to be simple and intuitive. In the past the classic visualization of electrophysiological signals was done by displaying the signal amplitudes over time. This needed minimum expertise in curve interpretation of evoked potentials. This display method proved feasible because the signals could be interpreted directly. In contrast, the positive reactions of autonomous nervous stimulation are harder to interpret. Refer to Figure 1 for a comparison of striated and smooth muscle reactions to direct nerve stimulation. Therefore, the most important and clear requirement was to get clear feedback of a positive answer. The user interface depicted the results of a complex signal processing routine in the form of visual clues and parallel audio signal feedback (see Figure 2) [4].

During the lifetime of the project, several additional requirements arose and led to changes of the developed system. Of course, this input came mainly from the user, most often the surgeon, but not only. In an early phase of the project, it became clear that neurophysiological needs were different than first thought [5]. Figure 3 illustrates examples of the different information stages of piONM®, especially in the very beginning. The nervous structure of the pelvic region is much more sophisticated than first thought (compare Figures 3 and 4). Although the understanding of the neuro-anatomic features is already comprehensive, many functions of the autonomous nervous system are still not yet fully understood to guarantee a safe medical OR system.

In addition, technical-wise, the first recorded data-sets were of poor quality compared to those delivered using the contemporary amplifying and filtering possibilities. In parallel to these fundamental changes, the developing and financial requirements were gathered and realized in a standard V-model of requirements engineering and adjusted to the different generations of the devices.

2.1 First generation and approach

As the operation strategy during TME changed and the tissue containing the nearby nerve structures is dissected [7] (see Figure 4) the urgent need for identification of nerves meanwhile TME arose as direct consequence of post-operative patient care. As consequence of this operation

![Figure 1: Upper curve (A) presents a muscle response signal of vocal cords after indirect stimulation. Lower picture (B) shows the increasing power content of the signal.](image-url)
strategy, the survival rate of cancer patients increased and the postoperative quality of life came even more into focus.

A needed and easy-to-use method for intraoperative monitoring was investigated with the aim to directly stimulate and identify the autonomous nerves. At first, existing stimulators were used. Afterwards, the ones supplied by medical companies as IONM devices offered the advantage of the integrated recording possibility and of course the CE certification as medical product. However, the usage of pressure sensing was not yet standard in IONM, although crucial for the application in pelvic monitoring. Direct nerve stimulation with bladder manometry and electromyography (EMG) of the sphincter muscles became later the standard.

Stimulation paradigms to elicit autonomous nervous structures are different than for motor or sensory nerves. The stimulation frequency is higher with approximately 30 Hz, also stimulation currents were chosen higher, in the range of 6–15 mA. As stimulation probes are different in design and having bigger surface areas, the current density remained in the same range. In addition, the recording paradigms had to be adjusted. Muscle recording in the frequency range of 50–250 Hz as main frequency content is standard in IONM. Smooth muscles instead have significant frequency peaks and much lower ranges, mainly between 0.1 and 30 Hz. Therefore, the amplifiers of the monitoring system had to be adjusted to perform reliably in this frequency range.

Also pressure sensing was introduced electronically: a pressure transducer was integrated in the monitoring system and approved as a medical product. With this solution, the first used open water column became redundant and handling in the OR much easier and safe, mainly because the open water system turned into a closed system. Although pressure sensing during intraoperative monitoring was new and never used before, the principles of the closed liquid system were well understood by the OR personnel and teaching of staff was focused on the differences of the intraoperative monitoring system instead. This made the introduction as a product feasible. Last but not least, the usability of all new devices and accessories were augmented by an adequate graphical user interface. This was designed according to the needs of the user [8].

### 2.2 Current devices

pIOM® during open TME is performed nowadays with a neuromonitoring system enabling bipolar electric stimulation of pelvic autonomic nerves under continuous EMG of...
the internal and external anal sphincter and manometry of the urinary bladder. For electromyography, bipolar needle electrodes are inserted usually under endosonographic guidance. Prior to neurostimulation, the bladder is filled with 200 ml of saline solution and connected to the interface box (see Figure 5). Intermittent neurostimulation was carried out with a bipolar microfork probe repetitively posterolateral, lateral, anterior and at the level of the pelvic floor.

2.3 Future devices

The pIOM® systems described in this contribution are only the first of their kind. In TME surgery, still not all needs are addressed. One open main topic to be addressed is the continuous monitoring in addition to the intermittent quality control. To achieve this goal, several techniques were tested [9] but their usability in the OR was lacking good performance. Currently, additional techniques will be investigated to provide continuous monitoring, comparable to thyroid monitoring or neurosurgical monitoring methods [1].

The overall system in terms of a recording and stimulation device and user interface is well established and, in its usage, easy to comprehend and apply. But new generations of hardware and software will follow. Graphical user interfaces have changed significantly in the past. Especially consumer electronics had a high impact on the requirements and needs of the user. Touch based devices of consumer electronics are suggesting easier to use systems and wizard-like structures, comparable to Figure 6 and this need has to be transferred to IONM and pIOM§ devices.

New developments will also be done for the accessories, even if existing types are very suitable for current operation techniques. So recording electrodes and stimulation probes will be available in new designs and may also provide additional features. As surgical techniques are changing and new surgical tools are introduced, the accessories will be adapted to the new tools and surgical techniques [10].

3 Conclusion

We established a functional system to intraoperatively monitor autonomous nervous signals in the pelvic region. The high quality of the surgical system addresses especially laparoscopic interventions, e.g. TME. As the development of a medical device is a complex task, the approach was based on an already existing system for intraoperative neuromonitoring. Within this scope, we could investigate a new generation platform to perform optimal
Figure 6: Example of Wizard-Like graphical user interface to guide through a procedure. In spine surgery the user can choose the level to monitor (A), is helped to place the electrodes (B), gets clear and interpreted feedback of the stimulation response (C) and is warned if anything is wrong (D).

During surgical interventions. We presented the first technical results, software algorithms, graphical user representation, the approach of stimulation, and recordings in the field of experimental surgery.

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References