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Sensor Integrated Instruments for Surgical Quality Assurance and Process Monitoring

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Abstract

Demographic changes will increase the number of surgical procedures in the next years. Therefore, quality assurance of clinical processes, such as the reprocessing of surgical instruments as well as intraoperative workflows will be of increasing importance to ensure patient safety. Surgical procedures are often complex and may involve risks for the patient. For fixation of screws, e.g. in case of pedicle screws, osteosynthesis plates or revision joint replacement surgery implants, the application of defined torques may be crucial in order to achieve optimal therapeutic results and minimal complication rates. In many cases, a subjective rating of the surgeon is necessary, as no adequate instrumentation is available. With the same subjective feeling, hammering or screwing in are performed to implant e.g. the acetabular component in total hip arthroplasty.

Our actual work is dedicated to the implementation and evaluation of functional prototypes of sensor-integrated instruments for specific types in combination with RFID technology for smart process optimization in the operating room as well as for reprocessing of surgical instruments and surgical management in combination with a knowledge-based planning, control and documentation system. Complementary (preferably wireless) sensors such for instrument identification, tracking or more complex measurements such as forces, torques, temperature or impacts during surgery as well as during reprocessing of reusable instruments could enable computer network based quality assurance in a much broader and comprehensive manner.

Within the framework of the OR.NET initiative, we follow the approach to integrate wireless sensors for measurement of temperature, force-torque as well as inertial sensors for orientation and impact control, depending on the specific type of application for monitoring of workflows during surgery as well as during reprocessing of reusable instruments and devices. The integration of smart surgical instruments into an open networked operating room based on the open communication standard IEEE 11073 knowledge-based workflow system, can help to improve the process and quality management.

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1 Introduction

Demographic changes will increase the number of surgical procedures in the next years (Debatin et al. 2013). Therefore, quality assurance of clinical processes, such as the reprocessing of surgical instruments as well as intraoperative workflows will be of increasing importance to ensure patient safety. Furthermore, hospitals need to reduce their costs through automated processes and efficient planning of ressources (personell, infrastructure and material). Surgical procedures are often complex and may involve risks for the patient. This especially holds in case of complex procedures with multiple instrument trays and various implant sets. If problems or errors occur during the surgical procedure, therapeutical outcome and patient safety can be compromised (Wirbel et al. 2014; Saleh et al. 2015; Meeuwis et al. 2016).

For fixation of screws, e.g. in case of pedicle screws, osteosynthesis plates or revision joint replacement surgery implants, the application of defined torques may be crucial in order to achieve optimal therapeutic results and minimal complication rates. However, in many cases a subjective rating of the surgeon is necessary as no adequate instrumentation is available. Over-tightening of the screws can cause bone damage or bone interface failure, may lead to a longer healing process or implant failure (Steiner et al. 2016; Aziz, SR et al. 2014; Ab-Lazid et al. 2014; Reynolds et al. 2013). With the same subjective feeling, hammering or screwing in are performed to implant e.g. the acetabular component in THA. The introduction of surgical navigation systems established position tracking and user guidance for certain task sequences and a limited number of instruments and interventions. However, complementary (preferably wireless) sensors such for instrument identification, tracking or more complex measurements such as forces, torques, temperature or impacts during surgery as well as during reprocessing of reusable instruments could enable computer network based quality assurance in a much broader and comprehensive manner. Surgical checklists recommended by the World Health Organization (WHO) significantly reducing complication rates (Haynes et al. 2009), may be supported by computer assisted workflow monitoring on the bases of networking sensor integrated smart instruments. This contribution introduces the OR.NET concept of an integrated monitoring based on open multisensory network of smart instruments.

2 State of the Art

Although computer-assisted systems and sensor integrated instruments are available, they are not used in broad clinical routine. Apart from classical navigated instruments tracked by position measurement, sensor integrated instruments e.g. based on RFID technology has been proposed for surgical monitoring and workflow analysis (Boehler 2016; Glaser et al. 2015).

Moreover, application specific sensorized instruments such as e.g. the PediGuard (R) instrument for the detection of pedicle bore perforations by electrical impedance measurement (Bai et al. 2013) provide not only the information on a potential perforation as such, but could also deliver information on the actual sequence of operation. Another example is the real time recording of surgical sponges and the tracking of actions of the surgical team by using radio frequency identification (RFID) sensors (Kranzfelder et al. 2012).

3 Approach

Within the framework of the OR.NET initiative (www.ornet.org) we follow the approach to integrate wireless sensors for measurement of temperature, force-torque as well as inertial sensors for orientation and impact control, depending on the specific type of application for monitoring of

workflows during surgery as well as during reprocessing of reusable instruments and devices. The integration concept is based on the open communication standard IEEE 11073 (Kasparick et al. 2015). RFID equipped instruments help to monitor automatically each step of operation and to provide related information on the central surgical workstation if needed. The option to perform bulk reading of RFID equipped instruments also enable to check completeness of instruments sets during reprocessing and packaging as well as during surgery while searching for a specific instrument in the local OR stock during an intervention. The OR.NET approach opens the door towards the Internet-of-Things (IoT) in the operating room, providing open standards for interoperability of different devices and multisensor networks for computer-assisted knowledge based workflow navigation and monitoring. Figure 1 and Figure 2 shows an exemplary panel of the OR.NET surgical workstation developed in our lab with the workflow navigation bar and integrated checklists.

Figure 1: Graphical panel with workflow bar (lower side).

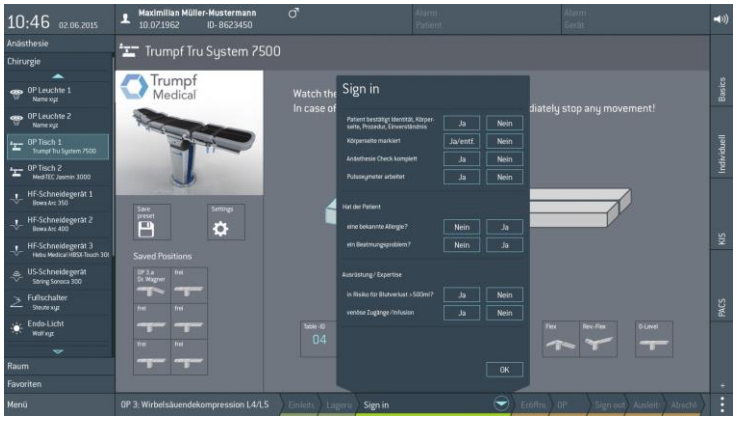

Figure 2: Surgical checklist of the OR.NET demonstrator.

The operating team or the surgeon are able to configure and document e.g. the patient information, diagnostic data, control available networked medical devices or use the workflow status from a touch-based graphical user interface (GUI) (Janß et al. 2014).

4 Conclusion and Outlook

The main objective of this paper was to propose the OR.NET concept of an integrated workflow management and monitoring based on open multisensor network of smart surgical instruments. Our approach intends to support and improve quality assurance and patient safety not only during surgery but also during reprocessing, storage and handling of instruments and devices. Our actual work is dedicated to the implementation of a functional prototypes of sensor integrated instruments for specific types of intervention (especially in traumatology) and the evaluation of the sensor integrated surgical instruments in combination with RFID technology for smart process optimization in the operating room as well as for reprocessing of surgical instruments and surgical management in combination with a knowledge-based planning, control and documentation system (Andersen et al. 2015).

The integration of smart surgical instruments into an open networked operating room based on the open communication standard IEEE 11073 knowledge-based workflow system, can help to improve the process and quality management (Kasparick et al. 2015). However, in order to benefit from the integrated technology, clinics, medical device manufacturers, research institutes and lead users have to work together in order to define specific requirements as well as standard operating procedures (SOPs) and guidelines for the different surgical disciplines and procedures as a ground truth for surgical workflow management and monitoring.

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