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The Intelligent ENT Operating Room of the Future*

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ABSTRACT

The increasing plurality and complexity of technical assistance systems pose a challenge for clinically active physicians. Particularly in the operating theater, there is a growing need to integrate medical systems and software solutions into a holistic clinical infrastructure. The primary goal of building a "digital (ENT) operating room of the future" is not just the pure technical improvement of the individual computer-aided equipment and instruments, but rather their dynamic networking and system integration in an open modular system. Promising scientific projects address the question of how to improve the quality, safety, and user-friendliness of technical systems in the health care system of the 21st century. The work on SCOT, MD PnP, and OR.NET show the various components that make the vision of the ENT operating room of the future tangible and realistic in the overall context.

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
BMBF	Bundesministerium für Bildung und Forschung (Federal Ministry of Education and Research)
BN	Bayesian networks
BPMN	Business Process Model and Notation
CI	Cochlea Implant (ation)
CIMIT	Center for Integration of Medicine and Innovative Technology
CPSI	Consistent and Prioritized presentation of Surgical Information
DIFUTURE	Data Integration for Future Medicine
DKFZ	Deutschen Krebsforschungszentrum (German Cancer Research Center)
FESS	Functional Endoscopic Sinus Surgery
HD	High-Definition
HiGHmed	Heidelberg-Göttingen-Hannover Medical Informatics
ICCAS	Innovation Center Computer Assisted Surgery
ICE	Integrated Clinical Environment
IIS	Institut für Integrierte Schaltungen (Institute for Integrated Circuits)
IKT	Informations- und Kommunikationstechnologien (Information and Communication Technology)
IT	Informationstechnik (Information Technology)
MAI	Modellbasierte Automation und Integration (Model-based Automation and Integration)
MD PnP	Medical Device Plug-and Play interoperability program
MGH	Massachussetts General Hospital
MIRACUM	Medical Informatics in Research and Care in University Medicine
MoVE	Modular Validation Environment
OntoRi	DeOntology-based Risk Detector
OR	Operating Room
ORiN	Open Resource interface for the Network
PRO	Patient Reported Outcome
SCOT	Smart Cyber Operating Theater
SDC	Service-oriented Device Connectivity
SMITH	Smart Medical Information Technology for Healthcare
SPM	Surgical Process Model
TATRC	Telemedicine and Advanced Technology Research Center der US Army
TNM	Tumor Classification: T = Tumor, N = Nodus, M = Metastases
TTM	Tumor Therapy Manager
WFO	Watson For Oncology

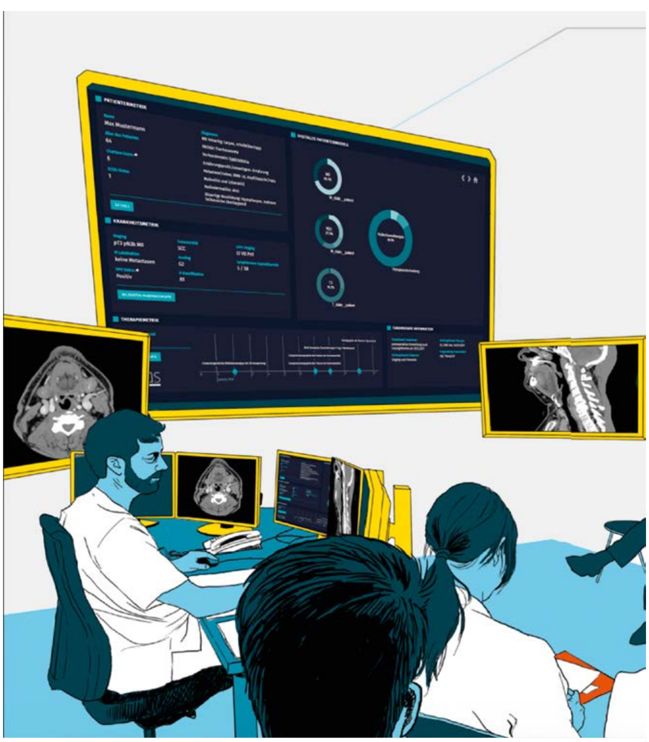
1. Introduction

Due to digital transformation and the application of artificial intelligence (AI) in diagnostics and therapy of medical issues, the profession of doctor is currently in a transition phase [21, 22, 39, 40] so that clinically active physicians of today and the future will have to face new challenges. In particular in the operating theater, this change becomes obvious because single concepts and components have made enormous progress based on isolated solutions of various manufacturers of medical products, but not every function is provided in the desired from as integrated complete solution. The surgeon and the staff in the OR have to cope with many (fragmented) applications (surgery microscope, HD endoscopes, drilling and navigation systems, neuromonitoring, even complex robotic systems such as the DaVinci system® [31], modern anesthesia techniques etc.) that communicate only to a limited extent and thus require sometimes complicated handling of a complex machinery that distracts from the core activity of the surgical team. In the context of digitization, the Innovation Center Computer Assisted Surgery (ICCAS) at Leipzig, Germany, has been dealing with the interoperability of medical technique as well as intelligent surgeon-centered information and technical assistance for many years and strives for solutions that are intended to "silently" support the surgeon based on the respective circumstances. The working title formulated as vision of "(ENT-specific) operating room of the future" is characterized by intelligent manufacturer-independent networking of medical technology, by safety and usability as well as intraoperative application of suitably accompanying information for the surgeon and the OR team.

Depicting the real OR conditions of today (▶ **Fig. 1.1, 1.2**) reveals the challenges for an intelligent operating theater of the future, in particular with regard to the pre-, peri- and postoperative setting. The use and usefulness of modern IT solutions can only be understood by the users when significant improvements in the operative process and the surgical results are obvious. Hereby, also healthcare economic aspects have to be taken into account, which gain increasingly in importance. There are for example numerous reports on the DaVinci® robotic system confirming significantly higher surgery costs because of the applied technique and the longer duration of surgery so that, at least with the background of economic efficiency, the regular application seems to be crucial for a hospital despite proven medical advantages [23, 24]. Unfortunately, controlled studies are not available for the last-mentioned telemanipulator system that might verify the significant superiority compared to current surgical procedures, as clearly explained in the much-quoted editorial by Jason D. Wright [56]. Thus, the discussion about the increasing healthcare expenses becomes more and more important due to the application of robotic procedures, which will have an always higher impact on the technical developments. The current science-based developments give reason to hope that the current implications of modular, open systems leading to increasing networking and communication of the systems do not only improve the surgeon's concentration and assistance, but also result in a reduction of the costs [1, 3](▶ **Fig. 2**).

This article will give an overview to clinically active ENT specialists about current aspects of technical research and its developmental steps, of information and communication technologies in the digital era of medicine. In this context, the fundamental questions regarding risks and benefits for the patients must be asked. How much technology is needed in medicine? Was healthcare without excessive (surgery) technique, colorful visualization on numerous screens, sophisticated navigation, and web-based data transfer really poorer?

▶ **Fig. 1** **a** and **b** Depiction of the typical scenery in ORs of today.



▶ **Fig. 2** Setting for preoperative preparation (figure taken from the ICCAS Annual Report of 2017 [80]).

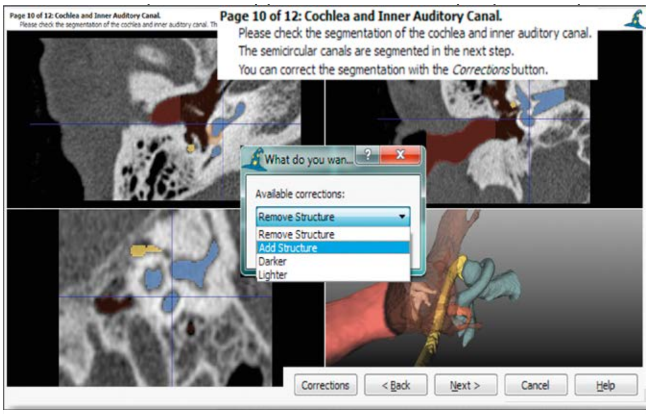
Where is this journey taking us? These questions and their answers will be discussed in the following paragraphs based on the 3 phases (pre-, peri-, and postoperative) of an (ENT-specific) surgical intervention and the summarizing description of concrete industry-sponsored projects on a national and international level.

For better understanding, the description of scientific results will be discussed in cooperation with the Department of Otorhinolaryngology of the University Hospital of Leipzig and the ICCAS at Leipzig.

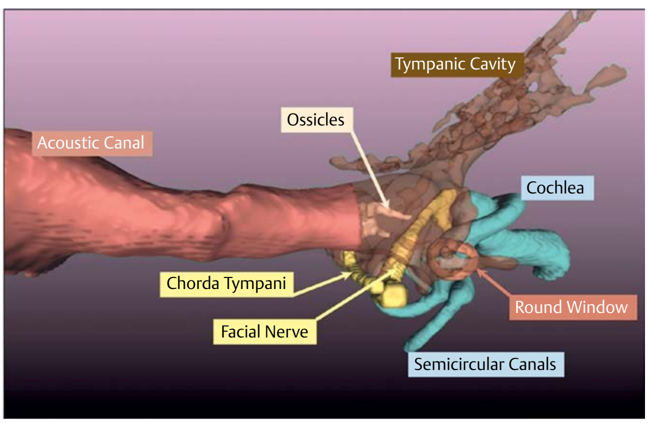
2. Preoperative tools in the operating room of the future

2.1 Visualization software

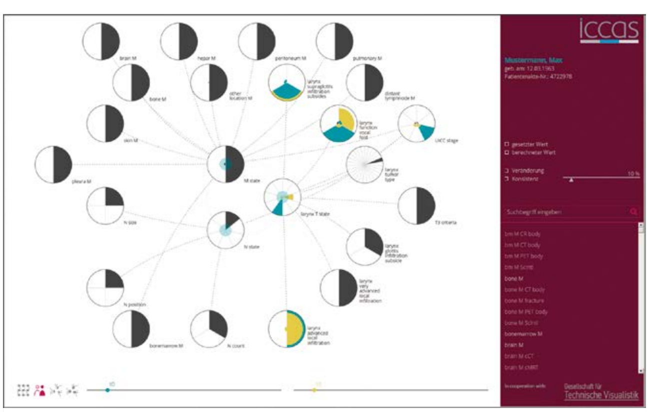
The improved visualization of patient-related data from imaging procedures in the preoperative phase is one of the core aspects of clinical basic research. The main objective hereby is the identification of risk structures, the discussion of anatomical variations as well as the calibration of data, especially in complex cases, for exacter surgery planning and hence an increased patient safety. In this context, new procedures are available with a specific focus on high accuracy and user-friendliness. In cooperation with the Department of Otorhinolaryngology of the University Hospital of Leipzig, Germany, and the Fraunhofer Institute of Erlangen, Germany, for Integrated Circuits, a 3D segmenting tool was developed based on the example of planning a cochlear implantation. This tool called "CI Wizard" served for improved preoperative visualization of the temporal bone (▶ **Fig. 3.1 and 3.2**). Based on the segmentation of specific risk structures of the lateral skull base by means of CT datasets, it was possible to confirm the clinical benefit and the user-friendliness of the program in the context of a clinical evaluation study [5, 41]. It could also be shown that the preparatory work with patient data led to a preoperative increase of the learning curve with regard to the complex anatomy of the temporal bone. For implementation in the clinical routine, it was particularly important to consider the time efforts that



▶ **Fig. 3.1** Overview of the CT segmenting tool called "CI Wizard" based on the example of 3D reconstruction of the marked structures of the lateral skull base (figure taken from [5]).



▶ **Fig. 3.2** 3D reconstruction of the marked structures of the lateral skull base in the CI Wizard (figure taken from [5]).



▶ **Fig. 4** Bayesian Network: the visualization tool presents a subset of the TNM staging network.

mentation in modern ENT ORs in that way that particularities in complex cases deviating from normal findings can be individually tested and visualized preoperatively. An improved visualization of preoperative staging images in head and neck cancer patients was the focus of investigations in clinical trials performed by Boehm et al. [6]. Hereby, especially 3D reconstructions and their integration by computer-assisted systems based on PET-CT data turned out to be helpful tools for differentiated discussion in interdisciplinary tumor boards for precise surgical as well as radiotherapeutic treatment planning, documentation, and study management. Another instrument for decision making and better surgery planning is the "Tumor Therapy Manager (TTM)" [44–46] evaluated by Pankau et al. [7], which is a software tool for preoperative 3D documentation and reconstruction. A comparison of "c" and "p" TNM in particular for the lymph node status provided a higher accuracy in cases of preoperative application of the 3D TTM. Thus, also tools of this type may be useful for future discussions in tumor boards in order to determine the extent of surgical interventions.

2.2 Digital patient and process models

Beside the aspect of visualization, also active efforts are undertaken in the research area of digital patient and process models. The increasing number of medical diagnostic and therapeutic options for complex diseases, e. g. in head and neck oncology, requires patient-specific therapy decisions and processes, which are prone to increase the chance to obtain better clinical outcomes. However, it is difficult to achieve this objective because of the quantity and variety of collected patient data and their fragmented storing with different media as well as the multitude of diversified therapeutic options. In the scientific experimental stage, projects of the ICCAS Leipzig address this research area by modelling decision processes and the development of systems supporting the decision making processes, patient-specific therapy process models, methods for extraction and structuring of relevant information from patient files, and standardized information models [4, 11–13]. In the context of working on a digital patient model for decision making (introduction into projects regarding artificial intelligence), laryngeal cancer was chosen as ENT-related example because a sufficient complexity could be expected for the model to be created. Methodically, the modelling was performed based on Bayesian Networks (BN) in two steps: 1) modelling graphic structures and 2) integrating probabilistic parameters [47]. The structures as well as the probabilities were manually modelled by experts based on existing guidelines and professional literature [4]. In the following, they were validated for the sub-model of laryngeal cancer [11]. In order to visualize the model, a software tool was developed in cooperation with the Gesellschaft für technische Visualistik (GTV, Society for Technical Visualistics) of Dresden, Germany, that supported also the verification process by comparing 2 individual patient models (▶ **Fig. 4**).

In a clinical evaluation trial, this software was analyzed retrospectively with 20 patient datasets with 2 calculated BN each, applying original and manipulated TNM classifications. The results of the study could reveal that the developed visualization software allows verifying the patient's case in an appropriate timeframe and reducing the probability of inexact (non-helpful) data due to an improved transparency and verifiability [12, 48]. Overall, this approach presented the technical feasibility and also the possible clinical integration of digital patient models for supporting therapy decision making in (preoperative) interdisciplinary tumor boards based on Bayesian Networks, which is also confirmed in the literature [62–64].

In order to support optimized decision making in oncology, numerous scientific efforts are undertaken such as the so-called "dashboard" sponsored by the BMBF (▶ **Fig. 5**). In a compact manner, the

► **Fig. 5** Patient-specific dashboard supporting the therapy decision making process (figure taken from ICCAS [80]).

► **Fig. 6** Surgeon-centered setting in the operating theater of the future (figure taken from ICCAS Annual Report 2017 [80]).

tool that had been developed presents data about the patient on 5 levels and refers to the above-mentioned Bayesian Networks in the context of the therapy decision making process ("patient inspector", "information quality metrics", "therapy timeline", "TNM staging", "decision model") [11, 28, 29]. This data collection already occurs in the clinically digital routine by means of web-based support systems for computer-assisted tumor diagnoses and treatment processes. Thus, especially in the head and neck tumor board, considerable benefit is achieved in the interdisciplinary communication (ENT, maxillofacial surgery, radiotherapy, nuclear medicine, neurosurgery, internal oncology, pathology). In the context of a research project at the ICCAS, the ENT Department of the University Hospital of Leipzig could successfully evaluate the scientific prototype called "oncoflow" since the end of 2012. Hereby, documentation could be made more transparent and the clinical processes more efficient [25–27] (► **Fig. 6**).

This interface is also addressed by large, industrially sponsored projects in the context of artificial intelligence (AI). Based on the examples of IBM Watson® (WFO – Watson for Oncology) [65] or NAVIFY® by Roche [66, 67] already market-ready and commercially available products of data organization in oncology could be developed for use in interdisciplinary tumor boards. In clinical studies, efficient structures and high concordances between medical expertise and computer-based techniques could be confirmed [53–55]. Despite or perhaps due to the constructive linkage between industrial sponsoring (product development) and scientific research, this will be an increasing market that, in the near future, will play an important role for supporting decision making in the context of complex molecular biology and diversification of expensive individual therapy options in oncology that will have to be thoroughly selected.

3. Perioperative tools in the operating theater of the future

The rapid progress in the field of information and communication technology in medical techniques significantly modifies the requirements to a surgeon's workplace. Systems for intraoperative navigation and assisted guidance of instruments are intended to facilitate the surgeon's work without distracting the focus from the actual work.

3.1 Theoretical models for a surgical cockpit

The international research projects on implementation of a "surgical cockpit" include the development of concepts to design a "digital operating theater" where a technique is applied that is adapted to the individual surgeon's needs and that may be used effectively due to compatibility and communication of the single systems [1, 3, 9, 10]. On a national level, an ICCAS project groups called "Modellbasierte Automation und Integration" (MAI, model-based automation and integration) works on the development of a prototypic IT system for administration, control, and monitoring of surgery processes. The aim of the scientific efforts is a discipline-specific "surgical cockpit", which supports the surgeon in a comprehensive, situation-related, and intelligent way.

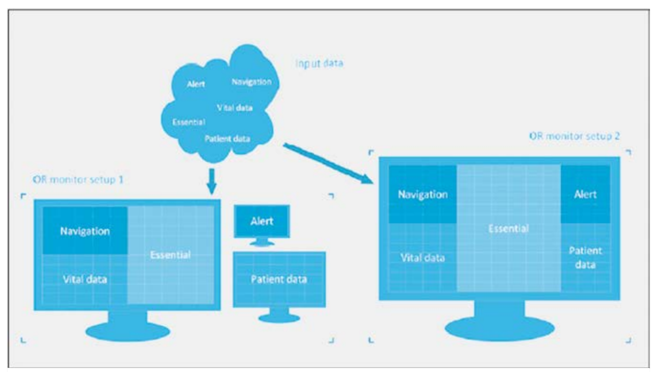
Automation of intraoperative processes and sequential data analyses are considered as prerequisites of computer-based interventions in modern integrated ORs. It is the question of providing the physician with relevant information about the current situation and to care for a situation-specific device configuration combined with other supporting services. For this purpose, intraoperative processes have to be programmed as surgical process models (SPMs). For a device-related interpretable depiction of so-called SPMs, the ICCAS clinically tested an updated "business process model and notation" (BPMN 2.0) in the OR. The result of theoretical efforts was an efficient model notation for the working processes in the integrated OR [15–17]. Further software tools for perioperative security monitoring and internal device communication are implemented in the OR in order to minimize failures in the working processes by the medical staff. Based on the example of cochlear implantation, the ICCAS evaluated the web-based software module called "Ontology-based Risk Detector" (OntoRiDe) that recognizes relevant risk structures based on definitions (ontology encompasses a representation, formal naming, and definition of the categories, properties, and relations between the concepts, data, and entities that substantiate one, many, or all domains), monitors the entire surgery process, and gives feedback by means of an alarm [18]. Currently, this security and alarm software and the oncologic model in general are checked with other surgeries in order to give a final statement on the practical benefit and to discuss the implementation in daily clinical routine [68–70]. Further research projects on the surgical cockpit aim at compressing the enormous amount of perioperative patient data by means of implemented software tools (e. g., in the context of the BMBF project "CPSI", Consistent and Prioritized Presentation of Surgical Information). These components that are interposed between the OR network and the monitors lead to a selection and reduction of the data by automated switching of surgical information depending on their relevance for the current surgery situation. In a clinical case of functional endoscopic sinus surgery (FESS), the ICCAS evaluated a description with adaptation of the available information in the setup with 2 displays (▶ **Fig. 7**) that the surgeons rated as very positive and efficient for the working process.

3.2 Theoretical models for surgical assistance systems

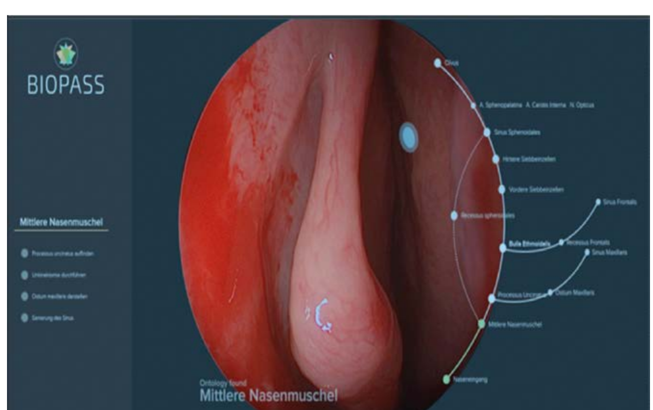
Regarding the numerous technical assistance systems that are available on the market, the current theoretical research efforts are primarily aiming at improving the integration and system networking. As an example, in the project entitled "Context Aware Medical Assistance" the ICCAS could create a setup that should control the interoperability as well as the working process in the OR. In the context of clinical studies, the standardization process "IEEE 11073 SDC" [3] was conducted that is also applied in the OR.NET (see below). This international standard serves for realization of manufacturer-independent, interoperable networking of patient-near medical devices. In detail, this standard solution consists of a service-oriented communication technology, the so-called MDPWS (Medical Device Profile for Web Services), a domain information and service model, and a connector between the first 2 mechanisms. The system was tested in a total of n = 24 FESS (phantoms) with the result of an appropriate robustness of the implemented processing pipeline [1, 19, 20]. The principle of modular construction of the technical assistances was also applied in the multicenter project entitled "MoVE" (Modular Validation Environment) based on the standardized device description (IEEE 11073 SDC, service-oriented device connectivity) [3, 36, 37] in order to verify the transition from the theoretical idea to the clinical routine. This standard solution seems to be suitable for future networking open surgery systems with regard to market introduction [71].

Beside the above-mentioned standardization and networking models, there are new processes and approaches for minimally invasive endoscopic surgery in the context of primarily technical development of perioperative navigation. In the project entitled "BIOPASS" [8], for example, the model of the paranasal sinuses is used to combine endoscopic information with those of the surgery process and to implement it in situations that can be "learned" by the software. The intelligence of the software achieved in this way aims at supporting the surgeon with his work and at the same time to reduce the hardware-related requirements and fault effects. Current research efforts use the identified clinical and technical requirements to implement the primary functions for the BIOPASS system. A first prototype has been developed at the ICCAS to simulate specifically the interaction between the user and the intelligent software based on the example of FESS [8] (▶ **Fig. 8**). A particular focus is placed on the presented information and the navigation through anatomical regions in the endoscopy view. Further activities are undertaken to develop a demonstrator that combines the single functions of the contributing project partners with the objective to evaluate navigation without the necessity of additional markers, tracking cameras, and conventional imaging (for example CT scan, MRI). Taking into account the established systems, it has to be elaborated in further trials if the later implementation of this navigation concept in modern ORs appears to be realistic [72, 73] (▶ **Fig. 9**).

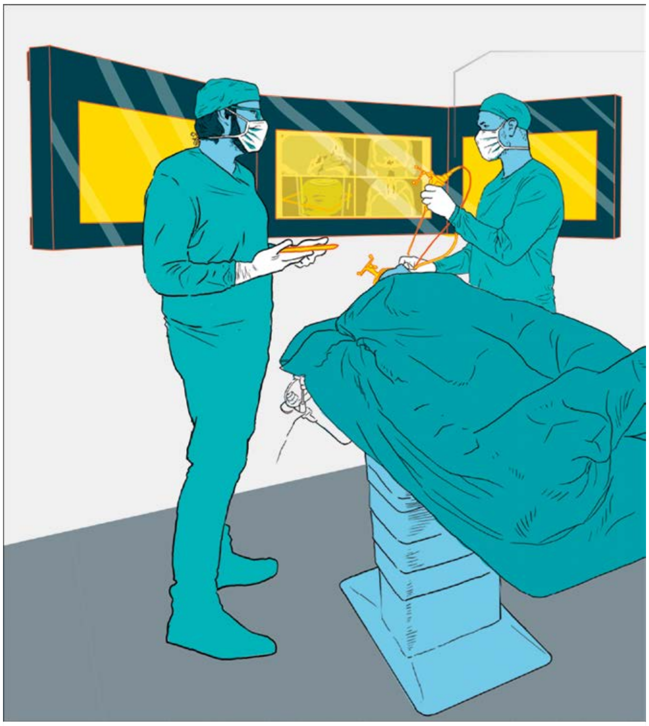
In the same way, these aspects touch other theoretical assistance models such as the "Equipment Management Center" [9] based on alarm- (acoustic, visual) and monitor-related assistance systems that



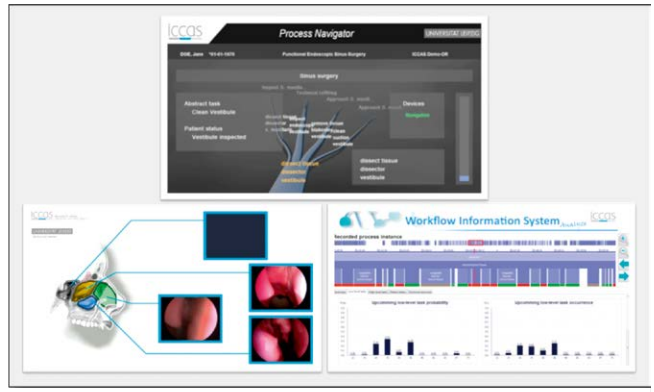
▶ **Fig. 7** Example for the assignment of category-based information to 2 different monitor setups (figure taken from ICCAS Annual Report 2017 [80]).



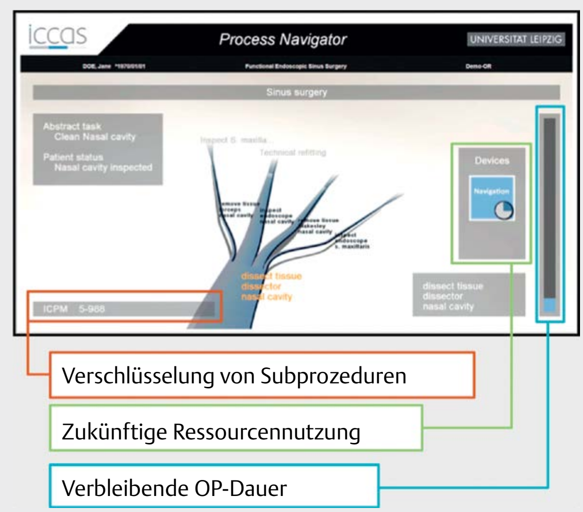
▶ **Fig. 8** Concept draft for the interface of the navigation system with different aspects of the analyzed surgical situational information (figure taken from ICCAS Annual Report 2017 [80]).



▶ **Fig. 9** Postoperative documentation starting in the perioperative setting (figure taken from the ICCAS Annual Report 2017 [80]).



▶ **Fig. 10.1** Workflow information system based on the example of FESS (figure taken from the ICCAS Annual Report 2017 [80]).



▶ **Fig. 10.2** Display of the information in the "Process Navigator". The pathways suggested by the system are depicted as well as the associated (sub-) procedures, future use of resources, and the remaining duration of surgery (figure taken from the ICCAS Annual Report 2017 [80]).

focus on the core aspect of preserving and improving the patient safety in an increasingly engineered and complex OR. In all technical development, this should be the highest priority.

4. Postoperative tools in the operating theater of the future

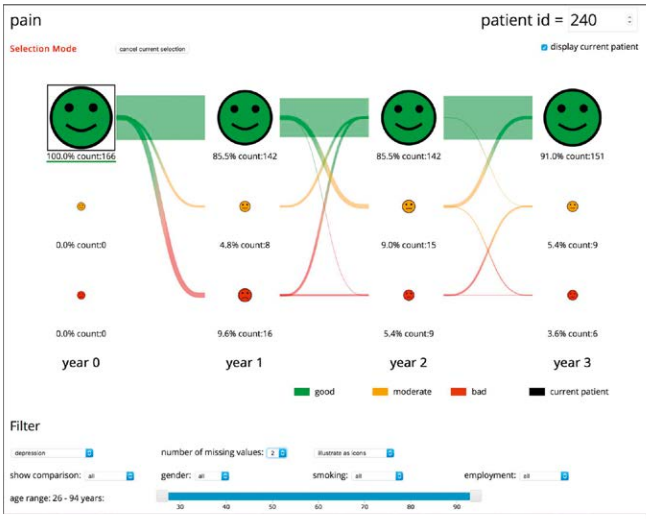
In the context of improving the operative processes, it is the objective to prepare postoperative documentation already during surgery by means of the described assistance systems as well as sequential storage of surgery data.

4.1 Postoperative documentation

The so-called data logging (see chapter 5) includes in particular a preoperative video and photo documentation that is intended to be used as pattern for surgery reports and others. Similar to the below-mentioned surgery projects, it is also planned to automatically insert text modules for surgeries, diagnoses, and procedures (if desired) into a respective mask. Thus, the workflow should be optimized which would represent a real benefit for the surgeon and the medical OR staff. Further it is possible to compensate (probable) preoperative additional time efforts due to technical preparations [3, 23]. Based on the example of the ICCAS "process navigator", the surgery pathways performed during FESS automatically lead to according postoperative steps (e. g., coding of sub-procedures, images of the surgery site) (▶ **Fig. 10.1, 10.2**). The technical realization in this field has reached a high level, taking into account national data transfer and data protection regulations (see below: SCOT, MD PnP, OP 4.1).

4.2 Follow-up in the context of cancer diseases

The fact that in particular complex oncologic patients benefit from a synopsis of the operative parameters in order to optimize the pathways for decision making and surgical interventions, is demonstrated by Müller and Zebralla et al. based on the recently discussed necessity to focus on the patient's subjective experience: "patient reported outcome" (PRO) [14, 43, 74]. Hereby, the software "Onco-Function" includes primarily functional data (e. g. information on dysphagia, dysphony, dyspnea, pain and B symptoms, psycho-oncologic comorbidities) retrieved from follow-up examinations of the patients in order to better and earlier recognize and plan necessary



▶ **Fig. 11** The interactive visualization of the individual patient over several years in comparison to all patients is depicted. A series of filters on functional disorders and psycho-oncologic comorbidities allows the continued development of further comparison groups (figure taken from [14]).

interventions resulting from consecutive functional disorders. Similar to the above-mentioned "dashboard", this screening tool also focuses on a rapid and comprehensive depiction of the data for the treating otolaryngologist (▶ **Fig. 11**). This project has already been implemented in clinical routine and is pursued for establishing a patient database.

While most projects and clinical trials approach to the pre- and perioperative setting, there is a high need to develop user-friendly application options in the postoperative sector which would be of great benefit in clinical routine.

5. From the project idea to the medical product: "the digital operating theater"

In the national and international environment of medical technology, already concrete scientific projects about the realization of an integrated and networking operating theater have been developed. Beside the mere product development and improvement, however, the processing of medical data and information plays a major role for implementation (see above). Also with regard to head and neck surgery, the research efforts of the last years in the field of medical informatics led to establishing integrative standards that are already applied today (among others DIFUTURE – Data Integration for Future Medicine; HiGHmed – Heidelberg-Göttingen-Hannover Medical Informatics; MIRACUM – Medical Informatics in Research and Care in University Medicine; SMITH – Smart Medical Information Technology for Healthcare) [49–52]. The objective consists of using identical services and functionalities in order to benefit in the best way possible from interoperability architectures and the planned process of data usage and access. For this purpose, alliances between hospitals, research institutions, and IT companies have to be established to avoid parallel structures. This aspect unifies medical informatics and medical technique, which will be elucidated in the following.

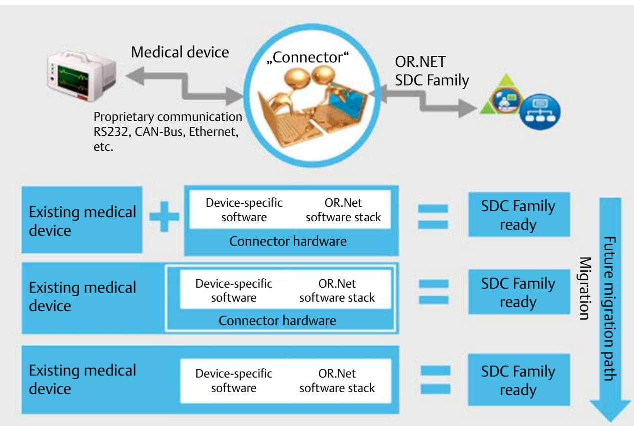
5.1 Smart Cyber Operating Theater (SCOT)

The Japanese government supports and finances the project entitled "Smart Cyber Operating Theater (SCOT)". Based on the example of neurosurgical interventions, already very concrete different medical products are interconnected in the system network on the basis of open resources interfaces. This concept called "ORiN" (Open Resource interface for the Network) was initially developed for the industry and turns out to be suitable also for medical issues due to its high flexibility [30]. "ORiN" as basic communication tool between operative assistance systems provides a standardized access model including data depiction and it may interact with different devices, independently from the model or the manufacturer. In the SCOT project, researchers are currently working on the extension entitled "OPeLINK" [30, 32] that opens the system for other manufacturers and standards. In this system, intraoperatively recorded data are available via the server ("client server system") also for postoperative use by third parties (e. g., imaging, surgery times, surgical procedures etc.,), which, however, has to be considered as critical for the European and especially for the German market because of very strict data protection guidelines [39, 75, 76]. Using those technologies, the Japanese colleagues further develop new applications such as recording treatment protocols and establishing treatment databases, optimized decision making by means of navigation systems, or a precision-guided treatment system. In this way, surgical interventions shall be more transparent, comprehensive, rapid, and in particular exacter in order to increase patient safety [30]. Already today, the scientific-commercial SCOT system is characterized by a high market maturity, especially in comparison with the below-mentioned projects. However, it can nearly exclusively be purchased as all-in package and – despite OPeLINK – it is compatible with OR modules of other providers only to a limited extent [77, 78].

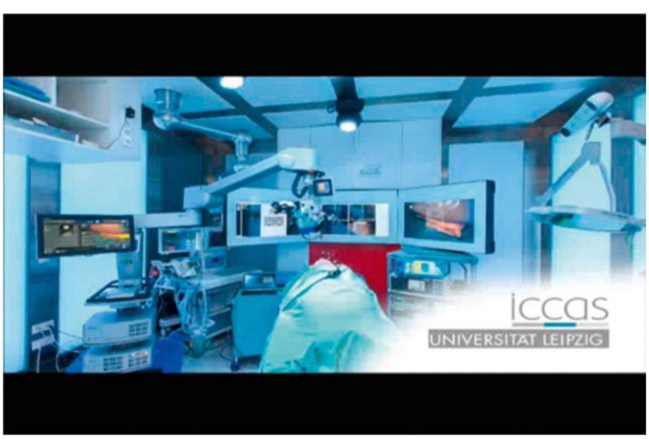
5.2 Medical Device Plug-and-Play Interoperability Program (MD PnP)

The counterpart in the context of US American research efforts is the "MD PnP (Medical Device Plug-and-Play Interoperability Program)" project founded in 2004 [33, 34]. Also hereby, the motivation was the current absence of an intranet-like system for connecting medical devices and clinical information systems. The clinical project is linked to the Massachusetts General Hospital (MGH), the CIMIT (Center for Integration of Medicine and Innovative Technology), and the partner "HealthCare System", additionally it is supported by TATRC (Telemedicine & Advanced Technology Research Center of the US Army). The US American researchers pursue the multifaceted approach in order to remove significant barriers of interoperability, including the development and support of suitable open standards (e. g., ASTM F2761–09 Integrated Clinical Environment; ICE) [35]. The objective of the principal investigators also include the definition of a secure patient pathway into the system network, the establishment and analysis of clinical scenarios as well as the subsequent implementation into clinical routine. The MD PnP program is currently in the experimental stage, however, the approaches and func-

▶ **Fig. 12** Official logo of the association called OR.NET (figure taken from [29]).



▶ **Fig. 13** Depiction of the connection (via "Connector Hardware") and update of medical assistance systems in the network of OR.NET based on the device standard of SDC (see below) (figure taken from ICCAS [80]).



▶ **Fig. 14** OR.NET demonstrator (experimental OR) at the ICCAS of Leipzig (figure taken from ICCAS Leipzig [80]).

tionalities are very promising [79] – similar to the projects described in the following.

5.3 OR 4.1

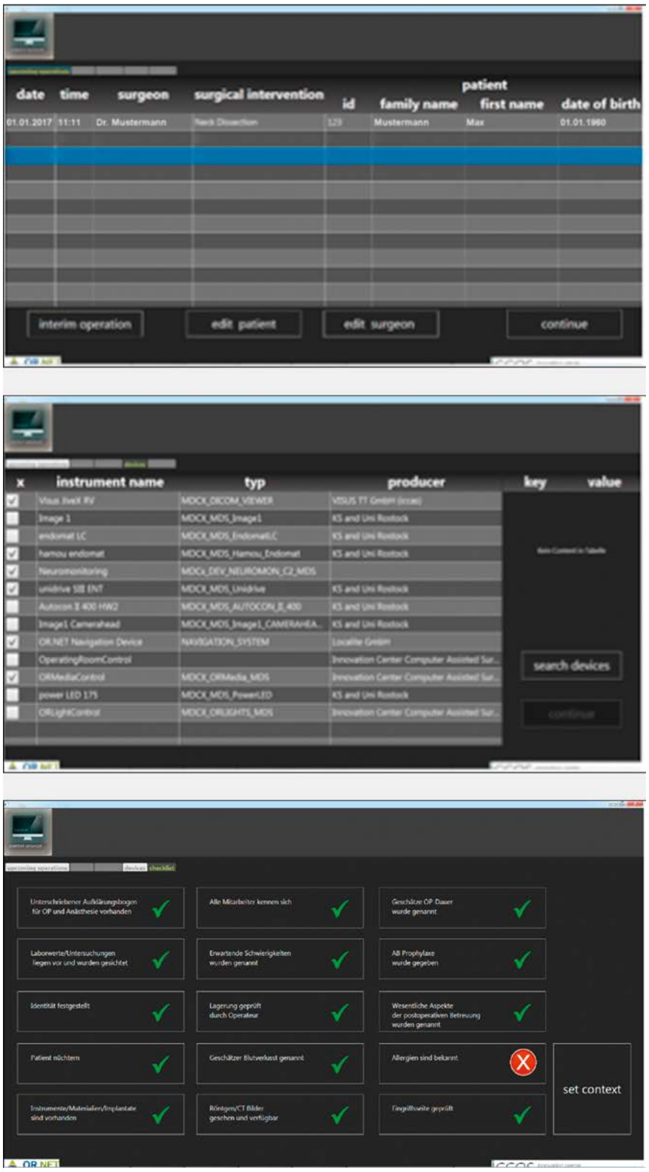
A kind of synopsis of the described operative aspects in the German-speaking area is found in the publications of OR.NET (see below) as well as – even with limited comparability – in the project OR 4.1. This project is conducted since August 2017 [38] and was initiated by the Department of Urology of the University Hospital of Heidelberg, Germany, in cooperation with industrial partners, the German Cancer Research Center (Deutsches Krebsforschungszentrum, DKFZ) as well as the Federal Ministry of Economic Affairs and Energy (Bundesministerium für Wirtschaft und Energie, BMWi Germany). In this context, surgical user concepts are investigated. The primary objective is to establish user-centered, open, and expandable software platforms in the OR. It is not the question of directly linking devices, in contrast to SCOT, MD PnP, and OR.NET. Based on the concepts of Industry 4.0, the OR 4.1 platform shall digitally integrate different process and patient data as well as provide the different protagonists in the OR environment with relevant information at the appropriate time. Similar to an operating system for smartphones, it is the aim to create a platform that allows companies of each size transferring new software solutions via apps into the OR in an efficient way. This common service-based integration platform shall be the basis for a simple implementation of research results into clinical practice and at the same time minimize the barrier for smaller, innovative companies to enter the market. Thus the project OR 4.1 is rather interested in actually realizing technical ideas than in basic research of innovative concepts with regard to interoperability, data and patient management.

5.4 OR.NET

Research and development for the OR.NET are currently summarized in the association called OR.NET that was founded based on the results of the BMBF joint project entitled OR.NET from 2012 to 2016 with more than 50 project partners (▶ **Fig. 12**) [29].

Similar to the SCOT and MD PnP projects, the association encompassing companies, hospitals, and research institutes, pursues approaches to a safe, automatic, and dynamic networking of computer-guided medical devices in the "digital OR of the future". Hereby, existing systems shall be further developed and updated, critically evaluated, and finally introduced into a standardization process. In this context, networking and interaction of the components with medically approved software represents a particular challenge to information and communication technology in the medical environment (▶ **Fig. 13**).

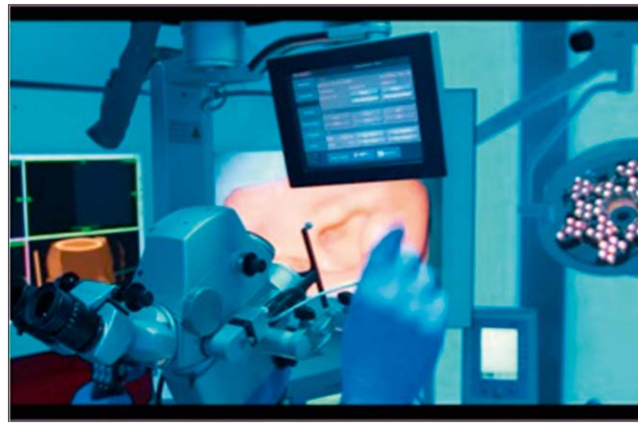
The overarching objective of technical development for medicine should be the improvement of the quality and safety in healthcare. Hereby, the safety and everyday suitability of networking medical products and IT systems is a central quality criterion as element of risk management. Due to the increasing technology and the complex man-technique interaction in the medical context, the consideration of this aspect gains enormously in importance. Those objectives are pursued by the association. Via the OR.NET project, numerous technical solutions could be realized up to now that reduce the described information surplus due to the plurality of different assistance systems as well as improve the missing system networking, OR documentation, and ergonomic problems for the surgeon [1, 3]. Such an OR.NET demonstrator has been implemented at the ICCAS of Leipzig that is suitable for scientific trials as research OR (▶ **Fig. 14**).



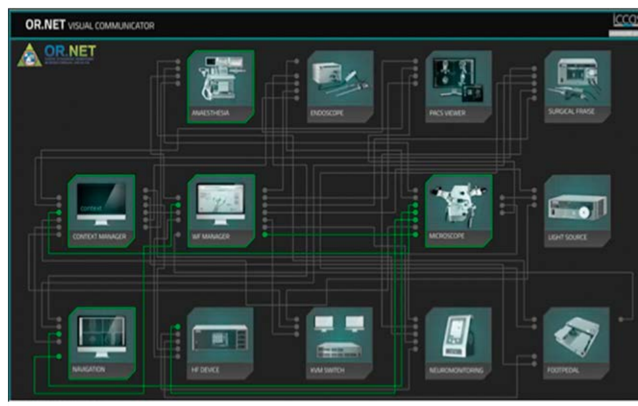
▶ **Fig. 15 a–c** Monitor input fields in the "context manager". (1) selection of the patient, surgeon, and surgery; (2) selection of the available medical assistance systems; (3) checklist before surgery (figures taken from ICCAS Leipzig [80]).

In the preoperative setting, the concrete technical particularities in the OR.NET include the so-called "context manager" to determine the session context by selecting the necessary medical devices, the current patient, and the respective intervention via tablet PC in order to retrieve pre-settings and profiles. With the transfer of the patient information to the selected devices, the preoperative aspect of the surgery is finalized (▶ **Fig. 15.1–15.3**).

Perioperatively, a central remote control of different medical devices and systems shall be implemented in order to ensure surgeon-fixed working [2]. By means of monitor(s) that are centrally and ergonomically installed as well as displaying relevant information (if desired) for example into the eyepiece of the microscope and the central upload of CT and navigation data, an undisturbed environment in the OR shall be created (▶ **Fig. 16**). Furthermore, networking systems such as intelligent mills, suction devices, surgical navi-



▶ **Fig. 16** Control of medical devices via monitors ergonomically installed at the microscope (figure taken from [3]).



▶ **Fig. 17** Network monitoring of medical assistance systems and data logging for sequential data storage of perioperative processes (figure taken from ICCAS Leipzig [80]).

▶ **Fig. 18** Ergonomic experimental setup of the technical components of the OR.NET in the ICCAS for ENT-surgical applications (figure taken from ICCAS Leipzig [3, 80]).

gation systems, adaptive light and other tools belong to the "thinking" inventory via the standardization software of SDC [2, 3]. in order to facilitate the surgeon's work (▶ **Fig. 17**) [80].

In addition, a so-called data logging (▶ **Fig. 17**) is performed perioperatively for sequential and complete data storage of the surgical parameters. In this way, the gap to postoperative documentation will be closed because the single surgery steps can be made more comprehensible and transparent. The aim is also to assess intraoperative procedures and diagnoses that are reflected in the pre-set surgery reports. All this will lead to improvements and in particular significant time saving in the postoperative course.

At the Department of Otorhinlaryngology of the University Hospital of Leipzig, the clinical evaluation of the OR.NET was performed in 2016 and 2018 together with the ICCAS demonstration of the "OR of the future" based on the examples of a rehabilitating ear surgery and cochlear implantation in order to transfer the theoretical idea into a practicable setting (▶ **Fig. 18**).

In 2 clinical studies, the preoperative management, the technical preparation of the OR, the course of surgery with phantoms, and the postoperative workflow were investigated for these ENT-specific interventions and evaluated by a total of n = 40 participants (trial 1: n = 5 ENT surgeons, n = 2 heart surgeons, n = 1 anesthesiologist, n = 2 OR nurses; trial 2: n = 15 ENT surgeons, n = 15 medical students). Qualitative questioning by means of structured interviews and quantitative interval-scaled questions were applied. In the first pilot study [3], the participants complained about the insufficient training regarding the handling of technical systems and integrated ORs despite the increasing significance in clinical routine. As core aspect of the future application, the hard- and software stability of open systems was mentioned. An increased patient safety (median: 7.5) as well as an improved intraoperative workflow (median: 9) could be confirmed by all participants. Even if n = 3 subjects expected a possibly longer OR preparation time, the finally observed OR time savings in an integrated OR were rated positively (median: 8). In the context of the second clinical evaluation trial based on the example of cochlear implantation in the OR.NET with phantoms compared to CI surgery in a "normal" OR, the workflow results in the OR.NET were highly positive. In the pre- as well as peri- and postoperative setting, the technical options and their linking with the process were rated consequently as "fairly helpful". The overall rating corresponded to "grade 2" (on a scale of 1–6 with 1 as best rating), with limitations of a complex "technical" working atmosphere and time savings that are not yet perceived as significant. In the context of prompt implementation of technical ideas, primarily partial implementations of the above-mentioned systems for OR.NET are in the focus. To achieve market readiness, further research is intensively fostered and developed (similar to other OR projects). Encouragingly, this includes also scientific partnerships, like between OR.NET and SCOT, in order to cooperate on the topic of "open networking of medical devices and IT systems in the OR and hospitals" and the accompanying technological challenges [80].

6. Concluding remarks

In particular the projects entitled OR.NET, MD PnP, and SCOT have the potential to integrate different technical medical products and assistance systems in a networking OR system based on open resources interfaces. In clinical trials, it was possible to show that treatment advantages may be expected in the pre-, peri-, and postoperative setting for clinically working physicians. In the era of increasing digitization also in the field of medicine, however, it must be critically discussed in how far surgical activities may actually be improved, how user-friendly the system are, how the timely efforts have to be valued, and which advantages for the patients are observed. Thus, intensive scientific studies and evaluations are required in cooperation with information technologists, engineers, and physicians. How much technology does a physician and medicine in general need in the 21st century? This question cannot (yet) be fully clarified with ultimate certainty. Based on the described developments, the recent innovations allow us to hope that the sometimes overstraining technical devices in the OR will perform their work "more silently" and actually ease the surgeons' activity. In summary, the "intelligent (ENT-) OR of the future" seems no longer a fictive idea, but an image of the realistic implementation in the sense of constructive, cost-effective, and patient-oriented modern medicine.

Conflict of Interest

The author states that there is no conflict of interests.

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