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Imaging meets Surgery – The Hybrid OR

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Abstract

Introduction: The merger of interventional and open surgical procedures leads to novel approaches in various clinical fields. Imaging becomes a critical tool and success factor because it allows for visualization of the targeted anatomical structures and leads the way for the clinician. Moreover high-end imaging (Angiography, CT, MRI) available in the operating room allows for assessment of treatment results immediately at the point of care which helps to avoid complications and the need for revision surgery. **Methods:** Operating rooms in various clinical fields are equipped with high-end imaging systems. The most prominent example is the angiography system in cardiovascular operating theatres. Requirements for imaging and other medical equipment vary among clinical specialties. Infrastructure and building technology are also important topics for planning and implementation. Workflow and hygienic requirements should not be forgotten. Thus building a hybrid OR is a complex technical challenge. Based on the experience of more than 400 installed angiography systems in Operating Rooms in more than 30 countries worldwide we have put together lessons learned and recommendations for planning and implementation. **Results:** Planning needs to consider all aspects and components from building technology to medical equipment. Early planning and room design with all stakeholders and balancing clinical requirements and technical feasibility is critical for success. Hygienic requirements vary significantly and therefore should be discussed and considered according to local regulations. Space in the OR is of essence. Irrespective of the angiography system a minimum of 70 m^2 is recommended to accommodate the complex workflows and equipment needs. **Conclusion** A hybrid operating room is a highly specialised workplace with very customer specific requirements. The boundary conditions and clinical requirements define the best design and concept for the room. Comprehensive application training on how to use the room and the equipment are mandatory to enable the proper use of the new surgical workspace – hybrid OR.

1 Introduction

The integration of interventional and surgical techniques is demanding a new interdisciplinary working environment: the hybrid operating room, where angiographic imaging capabilities are integrated in an operating theatre. The imaging capabilities of modern C-arm technology have dramatically changed in the last five years. Traditionally, C-arms have been used either for simple 2D fluoroscopy or 3D rotational angiography. Nowadays, C-arms, which are able to acquire CT-like 3D images, are used for image-based guidance and even provide intra-operative functional imaging, like flow analysis. A deep understanding of the clinical applications, the current and future technology, and their implications on workflows is needed for a sound room design. Hybrid operating rooms outside cardiovascular therapies are currently more and more used in neurosurgery, traumatology, orthopedics, urology, and general surgery. Interdisciplinary usage may be considered. Imaging needs, hygienic requirements, and room set up - particularly for neurosurgery - may be considerably different. Other surgical disciplines may want to introduce navigation systems, magnetic resonance imaging, endoscopy, biplane angiography systems, or a lateral position of anesthesia equipment. However, the hybrid operating rooms are more commonly shared with interventionalists including cardiologists, interventional radiologists, electrophysiologists, neuroradiologists, and pediatric cardiologists. Their specific needs have to be carefully considered and weighted when planning the hybrid theatre.

2 Methods

Careful planning and professional expertise is a key factor for every hybrid room project. Before planning a hybrid operating room a clear vision for the utilization should be established (Benjamin, 2008). Today's operating rooms require concepts that address the requirements and needs of different surgical specialties and procedures. Workflow efficiency is a key success factor for the hospital and the surgical program. Minimal turnover times and optimal processes throughout the entire surgical workflow and the actual surgical procedure are required (Tomaszewski, 2008). Based on the experience of more than 400 installed angiography systems in Operating Rooms in more than 30 countries worldwide we have put together lessons learned and recommendations for planning and implementation.

3 Results

A hybrid operating room should ideally be integrated into an existing OR suite. All aspects and steps starting with patient transfer from the ward to anesthesia and operating room preparation are important. Additional aspects for planning are material supply processes, i.e. of materials necessary for the procedure, and postoperative intensive care surveillance and treatment. A very flexible room layout and design allow for the necessary repositioning of devices and changes of the OR configuration (Tomaszewski, 2008). This is especially important with the increasing utilization of novel technologies and with space limitations

in most OR suites. Layout and design should be ergonomic and workflow driven. For the hybrid OR with the addition of an angiography system to the room it becomes even more important, because this often involves non-standard installations, or non-standard functionality, or non-standard products. During the entire planning and implementation process clear, frequent and comprehensive communication of all parties involved is vital. Building a hybrid operating room needs a team approach with joint effort of customers and vendors (Tomaszewski, 2008; Benjamin, 2008).

4.1 Team

Hybrid operating rooms are always individual solutions tailored to the needs and preferences of the team and the hospital. Several planning iterations with experienced technological support from equipment and imaging vendors lead to an optimal solution. Hybrid OR projects involve renovation, new construction, or a little of both. OR equipment layout planning and implementation strategies are challenging. A clear understanding of the project scope and customer objectives is critical and qualified, multidisciplinary hospital team is needed to ensure success of this complex endeavor. All team members should be committed to the project. To that end, a clearly defined and agreed project organization including all stakeholders with clearly defined roles and responsibilities is necessary.

4.2 Choosing the angiographic system

Choosing the imaging system for a hybrid OR depends on the intended utilization of the room (Bonatti et al., 2007; Ten Cate et al., 2004). Expert consensus rates the performance of mobile C-arms in hybrid ORs as insufficient and recommends floor-mounted systems for hygienic reasons (Bonatti et al., 2007). In fact, some hospitals do not allow operating parts directly above the surgical field, because dust may fall in the wound and cause infection. Since any ceiling-mounted system includes moving parts above the surgical field and impairs the laminar airflow, such systems are not the right option for hospitals enforcing highest hygienic standards. Ceiling-mounted systems require substantial ceiling space and, therefore, reduce the options to install surgical lights or booms. Nonetheless, many hospitals choose ceiling-mounted systems because they cover the whole body with more flexibility and – most importantly – without moving the table. The latter is sometimes a difficult and dangerous undertaking during surgery with the many lines and catheters that must also be moved. Moving from a parking to a working position during surgery, however, is easier with a floor-mounted system, because the C-arm just turns in from the side and does not interfere with the anesthesiologist. The ceiling-mounted system, by contrast, during surgery can hardly move to a parking position at the head end without colliding with anesthesia equipment. In an overcrowded environment like the OR, biplane systems add to the complexity and interfere with anesthesia, except for neurosurgery, where anesthesia is not at the head end. Monoplane systems are therefore clearly recommended for rooms mainly used for cardiac surgery. There are certainly exceptions: especially if pediatric cardiologists or electrophysiologists are important stakeholders in room usage, a biplane system may also be considered (Bonatti et al., 2007; Tomaszewski, 2008).

3D imaging may become more and more important for OR planning and postoperative evaluation of the operative site. Therefore, a large detector would offer greater options, including portrait imaging. The preference for a detector may vary, although the majority opts for a large detector (Nollert & Wich, 2008).

In summary, mobile C-arms are generally considered insufficient for cardiovascular imaging and do not comply with international standards for cardiac imaging (Bonatti et al., 2007). For hybrid rooms, fixed monoplane and biplane angiographic systems are available which are either mounted on the ceiling or on the floor. Beside conventional C-arm systems, a dedicated robotic surgical C-arm is available, which allows maximal flexibility in the operating room.

4.3 Tables

The selection of the OR table depends on the primary use of the system. Interventional tables with floating table tops and tilt and cradle compete with fully integrated flexible OR tables. Identification of the right table is a compromise between interventional and surgical requirements (Bonatti et al., 2007; Nollert & Wich, 2008). Surgical and interventional requirements may be mutually exclusive. Surgeons, especially orthopedic, general and neurosurgeons usually expect a table with a segmented tabletop for flexible patient positioning. For imaging purposes, a radiolucent tabletop, allowing full body coverage, is required. Therefore, non-breakable carbon fiber tabletops are used. Interventionalists require a floating tabletop to allow fast and precise movements during angiography. Cardiac and vascular surgeons, in general, have less complex positioning needs, but based on their interventional experience in angiography may be used to having fully motorized movements of the table and the tabletop. For positioning patients on non-breakable tabletops, positioning aids are available, i.e. inflatable cushions. Truly floating tabletops are not available with conventional OR tables. As a compromise, floatable angiography tables specifically made for surgery with vertical and lateral tilt are recommended (Ten Cate et al., 2004). To further accommodate typical surgical needs, side rails for mounting surgical equipment like retractors or limb holders should be available for the table. The position of the table in the room also impacts surgical workflow. A diagonal position in the OR may be considered in order to gain space and flexibility in the room, as well as access to the patient from all sides. Alternatively, a conventional surgery table can be combined with an imaging system if the vendor offers a corresponding integration. The operating room can then be used either with a radiotranslucent but not breakable tabletop that supports 3D imaging, or with a universal breakable tabletop that provides enhanced patient positioning, but restricts 3D imaging. The latter are

particularly suited for neuro- or orthopedic surgery, and these integrated solutions recently also became commercially available. If it is planned to share the room for hybrid and open conventional procedures, these are sometimes preferred. They provide greater workflow flexibility because the tabletops are dockable and can be easily exchanged, but require some compromises with interventional imaging. In summary, important aspects to be included considered are the position in the room, radiolucency (carbon fiber tabletop), compatibility, and integration of imaging devices with the operating table. Further aspects include table load, adjustable table height, and horizontal mobility (floating) including vertical and lateral tilt. It is important to also have proper accessories available, such as rails for mounting special surgical equipment (retractors, camera holder). Free floating angiography tables with tilt and cradle capabilities are best suited for cardiovascular hybrid operating rooms.

4.4 Lights

Ceiling space in a hybrid OR may be limited, particularly if a ceiling mounted system is preferred. Thus, OR lights need special attention, because they may collide with the imaging systems, pendants or display booms (Tomaszewski, 2008). In general, two different light sources are needed in an operating room: the surgical (operating) lights used for open procedures and the ambient lighting for interventional procedures. Particular attention should be paid to the possibility to dim the lights. This is frequently needed during fluoroscopy or endoscopy.In summary, the key topics for planning the surgical light system include:

- Central location above the OR table (impossible with ceiling mounted systems)
- Usually three light heads for optimal illumination of multiple surgical fields
- Suspension accommodating unrestricted, independent movement and stable positioning of light heads
- Modular system with options for extension, e.g. video monitor and/or camera

4.5 Hygiene

The operating room has different and stricter hygienic requirements and standards to meet than an interventional suite. Recently, hygiene has become a strong focus in addressing quality of healthcare delivery (Kerr, 2009; Hirsch, 2008; Sikkink et al., 2008; Peeters et al., 2008). Several workflow related aspects are crucial for achieving optimal hygienic conditions in operating rooms. A surgical scrub facility immediately outside of the OR is mandatory to allow proper scrubbing in for all procedures. Hats, gloves, facemasks and proper gowns are mandatory, as well as access sterile processing facilities for the disposal of soiled material from open procedures. Finally, clean air, air conditioning and ventilation technologies play an important role in achieving these hygienic standards. Today, this is mainly achieved with dedicated air-conditioning and ventilation solutions that create a limited protection zone, usually called “Laminar Airflow”, even though this terminology might sometimes be technically misleading. These ventilation systems need to cover the entire aseptic environment of surgery in operating rooms, including the tables for materials and instruments. This zone allows for clean-room handovers of sterilized materials and shields the surgical team in sterilized garb, usually by a sufficiently large low-turbulence displacement air flow. Recent guidelines, e.g. in Germany, emphasize the importance of low turbulence. To meet the requirements of air cleanliness for operating theatres or other surgery rooms with strict hygienic requirements, very high volume flows of clean air are necessary. There are different solutions available to do so in an energy-efficient way. Usually, low-turbulence displacement circulating air canopies are employed. Local requirements for the hygienic aspects of HVAC vary significantly. Experts knowing the local requirements need to be involved in order to ensure clearance of the hybrid OR at the end of the project. This topic is to be discussed in detail with the responsible individuals and authorities in order to avoid non compliance with local regulations.

4.6 Room layout

The main objective of OR design is to improve the OR workflow and enhance safety by ensuring good access and clear walkways. This sets the stage for equipment and equipment planning in the OR. Devices should be easy and quick to position and park. The limited space must be utilized optimally. Ergonomic aspects are to be considered for layout and design, which should enable flexible device management to cater to the needs of the various users and procedures. A clear floor and optimized cable management allow for efficient cleaning and easier maneuvering of devices. Moreover, this avoids tripping hazards. Camera and monitor systems for displaying patient data, for educational purposes or for telemedicine, may be necessary. Thus, and because of the complex needs for viewing during hybrid procedures, a good understanding of the visualization needs is vital. Data integration and IT are becoming more and more prominent for documentation, archiving and information provision. Current recommendations for hybrid operating rooms suggest > 70 m^2 in comparison to 40-60 m^2 for conventional operating rooms (space for a control and a technical room has to be added). The room has to fulfill radiation safety requirements as any other angiography room. A key part of any conceptual design is to visit other institutions that have built a hybrid OR (Benjamin, 2008). Thereby, customers learn from best practice and understand what works best for others and what other sites would have done differently if they could do it again. Topics include type of storage space, type of angiography system, handling of the patient flow and anesthesia services, control room concept, sufficiency of space, the type of inventory control and storage they have, and usage of barcodes or infrared technology. Storage capabilities are especially important. Oftentimes there will be no personnel available to fetch devices stored outside the OR. Build-in

glass cabinets have proven to be particularly useful because they allow the nurses to quickly locate materials. Design includes the following steps and activities (Tomaszewski, 2008):

- Define your current and future workflow and setup
- Start with a generic standard/sample layout of a hybrid room with the considered imaging system as a general guideline
- Involve all stakeholders (scrub nurses, technicians, surgeons, anesthesiologist, etc.)
- Cooperate with all vendors involved in the project

4.7 Planning process

The standard OR-layout is defined by the centrally positioned OR table and required access areas to the patient for anesthesia and surgery. In the hybrid OR the position of the angiography system and the table set the stage for the workflow inside the room. Other equipment follows this framework. Planning should always be done in 2D and with CAD, because this is the only way to identify all technical interdependencies and to allow for a reliable check of the technical feasibility of the installation. One single master plan across all equipment and vendors has to be created in CAD, while each vendor is meant to provide proper CAD blocks (Tomaszewski, 2008). However, 2D is usually not easy to "read", even for experienced planners. 3D visualization helps to illustrate the 2D plan, so that full understanding from all parties involved is ensured. Most medical equipment suppliers and architects have the ability to represent in 3D, such that all elements of the final outcome of the OR can be included in this visualization.

5 Conclusions

Building a hybrid operating room is a considerable economic investment for every hospital. Sound business models and optimal usage of the operation room are prerequisites to make this endeavour a financial success. A multidisciplinary approach is necessary to make best use of the hybrid OR and achieve the best patient and hospital outcomes. A key factor herein is a good working relationship between sometimes competing clinical disciplines. For example, cardiac surgeons and interventional cardiologists have to cooperate in numerous cardiac procedures such as TAVI. Multi-disciplinary case conferences in order to discuss the best treatment options are mandatory. Also, consensus and support from other functions in the hospital, such as anesthesia, intensive care, and hospital administration, are essential (Galantowicz & Cheatham, 2005). To support the process of implementing a hybrid program it makes sense to set up best practice teams (cardiac and vascular surgery, cardiology, nurses etc.) who jointly develop the approach in the hospital. Visiting other institutions with a successful hybrid OR in operation is a major help in the planning process. Learning from their experience and understanding their mistakes can help shorten the process for all involved staff

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