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The Hybrid Operating Room

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1. Introduction

The integration of interventional and surgical techniques is demanding a new working environment for an interdisciplinary cardiovascular team: the hybrid operating room, where angiographic imaging capabilities are integrated in an operating suite. A deep understanding of the clinical applications, the current and future technology, and their implications on workflows is needed for a sound room design.

2. Clinical applications in cardiovascular therapy

2.1 Definition of hybrid procedures

The definition of hybrid procedures in the literature varies widely. A strict definition of a hybrid procedure is a major procedure that combines a conventional surgical part including a skin incision with an interventional part using some sort of catheter-based procedure guided by fluoroscopic or MRI imaging in a hybrid room without interruption. Wider definitions include procedures where the interventional and surgical parts are done in sequence, where a surgical part is only necessary in case of emergency or even minor procedures as venous cut downs. Sometimes, fluoroscopy guided interventions performed by surgeons (e.g. endovascular aortic repair in aortic abdominal aneurysms) are referred to as hybrid procedures. The term hybrid procedure in the radiology world may also refer to the combination of two imaging modalities for diagnostics or therapeutic purposes. In this chapter, the strict definition of hybrid procedures is applied and only procedures with fluoroscopic imaging are included, as interventional MRI still is in its very early stage.

2.2 Pediatric cardiac surgery

Although surgery remains the treatment of choice for most congenital cardiac malformations, interventional cardiology approaches are increasingly being used in simple and even complex lesions. The percutaneous approach can be challenging due to low patient weight or poor vascular access, induced rhythm disturbances and hemodynamic compromise (Bacha et al., 2007). Difficult and complex anatomy as in double-outlet right ventricle or transposition of the great arteries, or acute turns or kinks in the pulmonary arteries of tetralogy of Fallot patients can make percutaneous procedures challenging if not impossible (Sivakumar et al., 2007). However, surgery also has its limitations. Examples are operative closure of multiple apical muscular ventricular septal defects, adequate and lasting relief of peripheral pulmonary artery stenosis, or management of a previously implanted stenotic stent. Combining interventions and surgery into a single therapeutic procedure potentially leads to reduction of complexity, cardiopulmonary bypass time, risk, and to improved outcomes. The hybrid approach to hypoplastic left heart syndrome serves as a role model of the hybrid concept for congenital heart disease. Extracorporeal circulation and deep hypothermic circulatory arrest in infants can be avoided (or at least shortened), as shown in the extensive experience of several groups (Bacha et al., 2006; see Fig. 1).

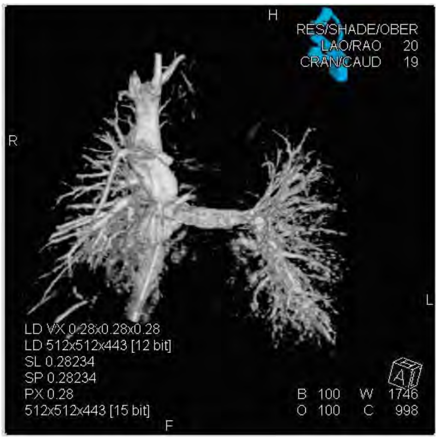

Fig. 1. Hypoplastic left heart syndrome. Intraoperative post-Fontan evaluation of the superior and inferior venae cavae as well as the stented pulmonary arteries. Imaging: Courtesy of Prof. Berger, Dr. Ewert German Heart Center, Berlin, Germany (Nollert et al., 2010)

Completion angiography in congenital heart diseases is another important concept. Residual structural lesions after cardiac surgery for congenital heart disease may complicate the postoperative recovery and result in poor outcomes. Therefore, intraoperative assessment of the newly created anatomy in 2D with fluoroscopy may help to avoid these complications. Rotational angiography with 3D reconstruction of the soft tissues (DynaCT) results in an even better delineation of the 3D anatomy and may change surgical strategy in a substantial subgroup of patients with CHD. Holzer and colleagues (R.J. Holzer et al., 2009) reported their experience with this imaging modality with 31 patients (median age and weight: 7.5 months and 6.5 kg, respectively) who underwent 32 complex surgical procedures, most of them involving pulmonary artery and/or aortic arch reconstructions. The angiograms were performed with regular catheters in a dedicated hybrid suite. Unexpected disorder was identified in 18 procedures (56%), including right and left pulmonary artery and coronary stenoses. The therapeutic strategy was modified in nine of 32 procedures (28%) and included surgical revision, hybrid therapy, early catheterization and a change in medical management. No major adverse events were noted. These advantages may be achieved in the operating room rapidly with fast image processing and even a reduction of contrast media and ionizing radiation dose (Pedra et al., 2011). The combination of an angiography system in the OR with magnetic resonance imaging may even further reduce dose and contrast and add additional functional data (Lurz et al., 2009).

2.3 Coronary artery disease

Routine evaluation of bypass grafts is the first indication for imaging in coronary artery bypass grafting. In a study designed and published by the Vanderbilt Heart and Vascular Institute (Zhao et al., 2009), routine intraoperative completion angiography performed in a fully functional hybrid operation room detected important defects in 97 of 796 (12% of the grafts) venous coronary artery bypass grafts in 366 adult patients (14% of the patients) with complex coronary artery disease. Their findings in completion angiography at the end of the operation included suboptimal anastomoses, poor lie of the venous bypass graft, and bypasses to not diseased vessels. The angiography findings led to a change in the management, including minor adjustments of the graft, traditional surgical revision or percutaneous coronary interventions, resulting in optimal bypass outcomes.

Surgical bypass grafting and percutaneous coronary artery revascularization are traditionally considered isolated options. A simultaneous hybrid approach may allow an opportunity to match the best strategy for a particular anatomic lesion. Revascularization of the left anterior descending artery with the left internal mammary artery is by far the best treatment option in terms of long term results. Integrating this therapy with percutaneous coronary angioplasty (hybrid procedure) offers multi-vessel revascularization through a mini-thoracotomy. Particularly in high risk patients, morbidity and mortality decreases in comparison to conventional surgery (Kon et al., 2008; Bonatti et al., 2008). A study from FuWai Hospital in Beijing (Hu et al., 2011) reports on 104 patients with multivessel coronary artery disease who were compared with the same sized group of patients undergoing off-pump surgery matched by propensity scores. The patients treated with the hybrid approach had a significantly lower ICU stay and intubation time and experienced less complications in terms of bleeding and transfusions needs. At a median follow up of 18 months, patients undergoing the hybrid procedure also had a significantly higher freedom from major adverse cardiac or cerebrovascular events (99 % vs. 90.4 %; $p = 0.03$). The hybrid procedure was also less costly than an exclusively percutaneous strategy.

2.4 Transcatheter aortic valve implantation (TAVI) procedures

Conventional aortic valve replacement for aortic stenosis is based upon standardized guidelines with excellent outcomes particularly in younger patients at relatively low-risk and will remain the gold standard for aortic valve replacement in the upcoming years. However, transcatheter techniques have developed to valid alternatives in high-risk patients in whom conventional surgical techniques are considered too invasive and risky. The Partner trial (Leon et al., 2010) using the Edwards Sapien valve demonstrated that patients with severe aortic stenosis, who are not eligible for conventional aortic valve replacement because of too high risk, benefit overwhelmingly from TAVI in comparison to standard therapy including valvuloplasty at one year in terms of survival (Cohort B, Leon et al., 2010). In addition, 700 enrolled very high risk patients undergoing TAVI for severe aortic stenosis had comparable mortality rates to those receiving conventional aortic valve replacements at one year (Cohort A, 25% vs. 26%). The transfemoral approach was used on approximately two-thirds of TAVI patients, while the transapical approach was used in the remaining third, unlike Cohort B where only the transfemoral approach was used.

Joint recommendations of the European Society of Cardiology and the European Association of Cardio-thoracic Surgery consider the hybrid operating room the optimal environment for these new therapeutic options (Vahanian et al., 2008). In Germany, joint recommendations of the German Society of Cardiology and the German Society of Cardiac,

Thoracic and Vascular Surgery demand a hybrid operating room or hybrid cathlab as a prerequisite for a TAVI program.
Currently two valves, the Corevalve (Medtronic, Minneapolis, MN) and the Sapien valve (Edwards, Irvine, CA) have been granted CE mark in 2007 and are successfully being implanted. Several newer generation valves aim to improve the results by more sophisticated designs to decrease the common current TAVI complications of aortic regurgitation, misplacement, and heart block. Advanced image guidance by dedicated 2D and 3D applications (e.g. syngo Aortic Valve guide, Siemens; Heart Navigator, Philips; C-THV, Paieon) may further simplify navigation and deployment of the devices. Some of the upcoming TAVI valves (e.g. Symetis Acurate, Jena Valve, Embracer, Medtronic) have dedicated mechanisms to anchor in the sinuses. Therefore, anatomically correct rotation of the valve within the aortic annulus is needed to optimally deploy the devices. 3D imaging may prove highly valuable to understand the correct relationships between the valve and the annulus.

2.5 Mitral valve repair

For repair of mitral regurgitation, various devices are currently under investigation and await FDA approval. Currently, it is also not quite clear which of the devices will be used in a hybrid operating room, because some approaches will most likely be performed in regular cathlabs. In Europe, only the MitralClip Mitral valve repair system (Abbott Vascular, Santa Clara, CA) has received CE mark in 2008. Studies for FDA clearance are ongoing. The MitralClip is creating a double orifice mitral valve by connecting the free edges of the anterior and posterior leaflets at the A2 / P2 level. The Everest II trial (Feldman et al., 2011) compared the MitralClip with surgical mitral valve with repair in patients with moderate or severe mitral valve surgery, who were candidates for mitral valve surgery and demonstrated superior safety at the expense of inferior efficacy. Experimentally, prostheses for mitral und tricuspid valve replacement are under development and certainly will be available within the next years. Complex hybrid procedures may arise where the various parts of the mitral valve apparatus (e.g. chordae, leaflet and ring) are repaired on a beating heart in combination with purely interventional techniques (e.g. MitralClip). For imaging purposes, fluoroscopy will most likely be combined with 2D and 3D ultrasound and a fusion of these modalities may become helpful. The reason is that the metal devices are optimally imaged without artifacts by fluoroscopy whereas the valve itself is better evaluated with ultrasound. As an alternative to transesophageal echocardiography, the use of intracardiac 2D and 3D echo (Accunav and Accunav V, Siemens AG Healthcare, Montainview, CA) may prove useful, because it would allow avoiding general anesthesia in selected patients.

2.6 Thoracic endovascular aortic repair (TEVAR)

Thoracic endovascular aortic repair (TEVAR) has become a valid alternative to open repair. In selected cases, EVAR, in combination with open surgery, is even applied for pathologies of the aortic arch and distal ascending aorta (Walsh et al., 2008). Endoleaks are common complications of EVAR and may be missed by angiographic evaluation. CT-like imaging with the angiographic C-arm enables the surgeon to diagnose this complication intraoperatively and correct it. A group from University of London (Biasi et al., 2009) demonstrated in a study of 80 patients undergoing EVAR that 3D imaging with DynaCT in the operating room was able to detect endoleaks in 5 patients. These endoleaks were not detected by conventional completion angiography. In addition, conventional CT evaluations before discharge did not reveal any endoleak which was not previously seen in DynaCT. In addition, the hybrid operating room allowed for immediate treatment of the endoleaks, if required. In the near future, off the shelf fenestrated aortic stents will become available for the treatment of extensive aortic disease. These fenestrated stents have to be rotated in the aorta, such that the fenestrations cover the branches of the aorta. For these highly complex procedures, 3D imaging in a hybrid operating room may be extremely helpful for the navigation of wires and devices.

2.7 Hybrid surgery for rhythm disturbances

The combination of the surgical epicardial approach with the interventional endocardial approach for the treatment of rhythm disturbances in particular atrial fibrillation offers theoretically advantages over conventional endocardial or epicardial therapy alone. First reports emphasized the potential benefit. Krul and coworkers from Amsterdam (Krul et al., 2011) reported on 31 patients with atrial fibrillation (AF); thereof 13 with persistent and two with permanent AF. A minimally-invasive approach combining thoracoscopic pulmonary vein isolation (PVI) and ganglionated plexus (GP) ablation with intraoperative electrophysiological confirmation of PVI was performed in order to decrease recurrences of AF during follow-up. Results at one year follow-up were very encouraging, with 86% of the patients without recurrence of AF. A hybrid approach for drug-refractory ventricular tachycardia was described by Michowitz (Michowitz et al., 2010). Fourteen patients (most of them after previous cardiac surgery) underwent surgical ablation with an epicardial approach with concomitant electrophysiological mapping. The authors conclude that the surgical access with subxiphoid window and limited anterior thoracotomy in the electrophysiology lab is feasible and safe.

Pacemakers and implantable cardioverter defibrillators (ICD), particularly bi-ventricular systems, may be optimally implanted in a hybrid OR environment, because the hybrid operating theatre offers the required superior angulation and imaging capabilities in comparison to mobile C-arms, and the higher hygienic standards compared to cathlabs. DynaCT angiographic 3D imaging may prove useful for imaging the venous system of the heart. The coronary sinus can be depicted in 3D and than be overlaid over the fluoroscopy image to better guide placement of the left ventricular lead.

2.8 Other applications outside cardiovascular therapy

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.

The need for hybrid operating theatres is not restricted to cardiac surgery. Vascular surgeons and neurosurgeons have equally developed hybrid procedures necessitating angiography systems in the OR. Furthermore, hybrid operating rooms are already in use by abdominal surgeons, traumatologists, orthopedic surgeons, and even urologists. 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.

3. Imaging techniques in the hybrid operating room

The imaging capabilities of modern, fixed C-arms have dramatically changed in the last five years. Traditionally, fixed 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.

3.1 Fluoroscopy

Traditional fluoroscopy provides real-time, high resolution, low-contrast images in two dimensions through the use of an image intensifier. With ultrasound and endoscopy it is the main imaging modality to guide devices in real time through the body (see Fig. 2a). Brilliant image quality is needed to depict fine anatomic structures and devices. In particular, in cardiac interventions, imaging the moving heart requires a high frame rate (30f/s, 50Hz) and high power output (at least 80kW). Thus, the image quality needed for cardiac applications can only be achieved by high powered fixed angiography systems. In modern fluoroscopy devices image intensifiers have been replaced with digital flat panel detectors which enabled fluoroscopy to transition into three dimensions, producing CT-like images (see below). Fluoroscopy is performed with continuous X-ray to guard the progression of a catheter or other devices within the body in live images. To minimize the doses for the patient and the surgeon, dose saving measurements are essential in modern fluoroscopy devices (see section 3.4).

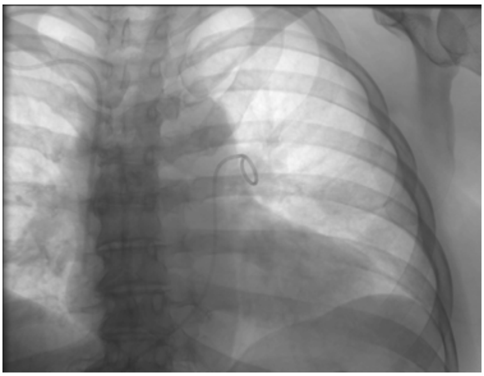

Fig. 2a. 2D fluoroscopic image

3.2 Data acquisition

Angiographic systems provide a so-called *acquisition mode,* which stores the acquired images automatically on the system to be uploaded into an image archive later. While standard fluoroscopy is predominantly used to guide devices and to re-position the field of view, data acquisition is applied for reporting or diagnostic purposes. In particular, when contrast media is injected, a data acquisition is mandatory, because the stored sequences can be replayed as often as required without re-injection of contrast media. To achieve a sufficient image quality for diagnoses and reporting, the angiographic system uses up to 10 times

higher x-ray doses than standard fluoroscopy. Thus, data acquisition is not recommended as long as fluoroscopy is sufficient or the images do not need to be stored.
Data acquisition can be combined with specific imaging protocols, for example, to enhance blood vessels while removing background structures (see section 3.3) or to acquire 3D images (see section 3.5).

3.3 Digital subtraction angiography

Over the past three decades, digital subtraction angiography (DSA) has become a well-established 2D imaging technique for the visualization of blood vessels in the human body (Katzen, 1995). With this technique, a sequence of 2D digital X-ray projection images is acquired to show the passage of an injected contrast agent through the vessels of interest. Background structures are largely removed by subtracting an image acquired prior to injection (usually called the mask image) from the live images (often referred to as contrast images). It is obvious that in the resulting subtraction images, background structures are completely removed only if these structures are exactly aligned and have equal grey-level distributions (see Fig. 2b). Therefore, various motion correction algorithms are applied to reduce such artifacts in the image.

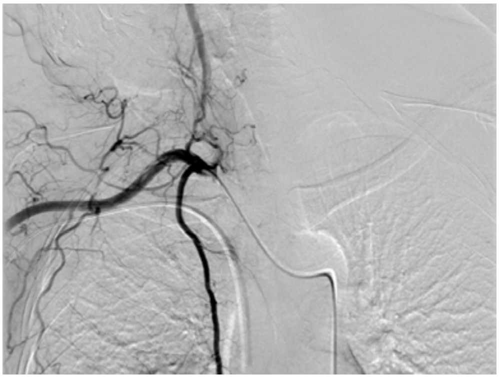

Fig. 2b. 2D digital subtraction angiography shows the difference between an initial fluoroscopic acquisition and a fluoroscopic acquisition after injecting contrast agent. Thus, the vessels are clearly depicted in these images. Other remaining structures (white next to black structures) caused by motion, are considered artefacts, and can be partly compensated by modern angiography devices.

DSA is clinically used for diagnostic and therapeutic applications of vessel visualization throughout the entire body. During complex interventional procedures, DSA is often combined with so-called *road mapping*. In this mode, a DSA sequence is performed and the frame with maximum vessel opacification is identified, which becomes the road map mask. The road map mask is subtracted from subsequent live fluoroscopic images to produce real-time subtracted fluoroscopic images overlaid on a static image of the vasculature. Road mapping is useful for the placement of catheters and wires in complex and small vasculature, because fluoroscopy alone may not adequately show the vessels and may not visualize small wires in the distracting underlying tissue. It is also possible to combine the road mapping feature with a feature called image fade, which allows the user to manually adjust the brightness of the static vessel road-map overlay.

3.4 Radiation dose and dose reduction

Ionizing radiation may, depending on the dose, cause damage to organic tissue. The mechanisms by which radiation damages the human body are two-fold: (1) radiation directly destroys the DNA of the cells by ionizing atoms in its molecular structure and, (2) radiation creates free radicals, which are atoms, molecules, or ions with unpaired electrons. These unpaired electrons are usually highly reactive, so radicals are likely to take part in chemical reactions that eventually change or harm the DNA of the cells.

The human body can repair damaged cells to a certain extent, but if exposed to a high amount of radiation beyond a given threshold in a short period of time, "deterministic" damage will occur. Deterministic radiation damage includes changes of the blood count, hair loss, tissue necrosis or cataract. Exposure levels of typical medical diagnostic imaging procedures are far below the threshold for deterministic radiation damage. However, deterministic effects are an important consideration in external radiation therapy and radionuclide therapy.

In order to assess the risk of radiation exposure, quantitative measurements of dose were introduced:

- *Absorbed dose D* (also called "energy dose"), measured in Gray (Gy) units, characterizes the amount of energy deposited in tissue. It is defined as the amount of radiation required to deposit 1 Joule (J) of energy in 1 kilogram of any kind of matter.
- *Equivalent dose H*, measured in Sievert (Sv) units, takes in account the damage caused by different types of radiation. It is the absorbed dose multiplied by a weighting factor characteristic for the particular type of radiation. For X-ray, H = D.
- *Effective dose E*, measured in Sievert (Sv) units, includes the sensitivity of different organs to radiation. It is the sum of the equivalent doses in all irradiated organs multiplied by the respective tissue weighting-factors.

Determining the effective dose in angiography depends on several factors, primarily on the variability in organ sensitivity to radiation. For instance, bone marrow is far more sensitive to radiation than the liver. The degree to which organs are affected by radiation also depends on the angle of the beams. Because dose distribution in angiography is not as "homogeneous" as it is for CT, these factors must be considered when estimating the damage caused by irradiation. The effective dose includes the sensitivity to radiation of the different organs. It is the sum of the equivalent doses in all irradiated organs multiplied by the respective tissue weighting-factors.

Effective dose provides a good comparison with natural background radiation, which is on average about 2.4 mSv per year. Typically, during a cardiac diagnostic intervention with 15 p/s, the effective dose per minute is 0.6 mSv (Cusma et al., 1999).

In general, low dose goes hand in hand with less visibility, while higher image quality requires, among other factors, a higher dose. To obtain a specific image quality, it is necessary to choose the "right" dose for the tissue being penetrated.

Because guidance of endovascular devices requires continuous X-ray, modern angiographic systems include several measures for dose reduction (Balter et al., 2010). There are three parameters which can be adapted by the user to reduce the radiation exposure:

1. *Footswitch on-time:* footswitch on-time controls how long the body is exposed to X-ray beams, thus how long the body is irradiated: less time means less radiation.
2. *Frame rate:* high frame rates are used to visualize fast motion without stroboscopic effects. However, the higher the frame rate, the more radiation. Therefore, it is best to keep the frame rate as low as possible, according to the clinical need. Modern

angiographic systems can adjust the frame rate downward in various steps, from 60 pulses per second (p/s) used in pediatric cardiology to 0.5 p/s in some systems for slowly moving objects. A reduction to half pulse rate reduces dose by about half. The reduction from 30 p/s to 7.5 p/s results in a dose saving of 75%.

3. *Source-Image- Distance (SID)*: according to the quadratic law and a requested constant dose at the detector, a greater distance between the source and the imager increases the skin dose. Rising SID from 105 cm (=SID 1) to 120 cm (=SID 2) increases skin dose (i.e. the dose at the IRP) by approximately 30%, if C-arm angles, table position, patient, and requested dose at the detector do not change. Fig. 3 illustrates the setup including the lower (SID = 105 cm) and the upper (SID = 120 cm) position of the detector.

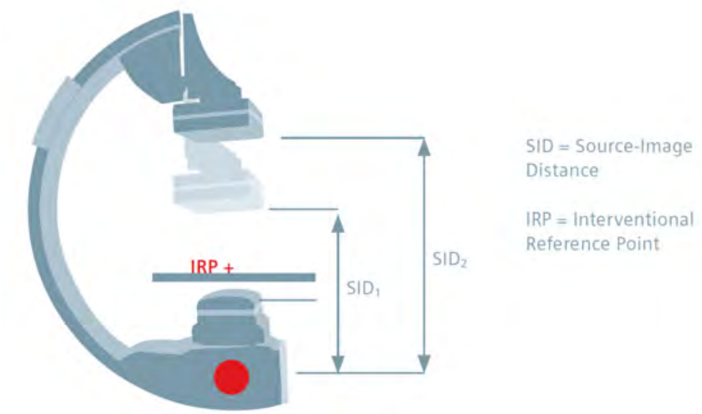

Fig. 3. C-arm, two different SIDs, constant table height, location of the IRP

Additionally, modern angiographic systems provide some inherent features to reduce dose. For example, variable copper filters reduce the skin dose by filtering the low-energy photons out of the X-ray, called *beam hardening*. Some systems adjust the thickness of such filters automatically according to the absorption of the patient entrance dose along the path of the X-ray beam through the patient. This automatic filter insertion maintains low skin dose without degrading image quality and can result in a dose saving of up to 50%.

Other measurements include radiation-free collimation or radiation-free object positioning. Using the last image hold (LIH) as a reference, the system allows radiation-free collimation and semitransparent filter parameter setting to precisely target the region of interest (see Fig. 4). A similar approach is implemented for optimal patient positioning for imaging: graphic display of the outline of the upcoming image allows translation of the table without fluoroscopic radiation exposure and provides an indication of which anatomy is in the field-of-view of the detector. For specific cardiac interventions, such measurements can reduce the overall fluoroscopy time by 0.5 to 3 minutes. Under typical fluoroscopy conditions, this may result in a dose reduction of 20 to 120 mGy.

More and more countries and authorities require the reporting of patient exposure to radiation following an intervention. To meet current and future regulations, modern angiographic systems allow effective reporting of dose exposure, thus enable enhanced in-house dose reporting and analysis.

Fig. 4. Radiation-free collimation: The collimator position is indicated on the last image hold (LIH) by a white frame.

3.5 3D DynaCT imaging

Three-dimensional (3D) C-arm computed tomography (DynaCT) is a new and innovative imaging technique. It uses two-dimensional (2D) X-ray projections acquired with a flat-panel detector C-arm angiography system to generate CT-like images (Kalender & Kyriakou, 2007). The C-arm sweeps around the patient acquiring up to several hundred 2D views serving as input for 3D cone-beam reconstruction. Usually, a minimum angular scan range of 180 degrees, plus the so-called fan-angle, is required. For typical C-arm CT devices, this results in an angular scan range requirement of at least 200 degrees. Resulting voxel data sets can be visualized either as cross-sectional images or as 3D data sets using different volume rendering techniques.

Thanks to a detector optimized for high-resolution 2D fluoroscopic and radiographic imaging, the spatial resolution provided by DynaCT can be very high. For example, a common FD for large-plate C-arm systems, such as the 30 cm × 40 cm Pixium 4700 flat-panel detector (Trixell, Moirans, France) offers a native pixel pitch of 154 µm in a 2480 ×1920 matrix. Due to read-out bandwidth limitations, such detectors are operated in 2 × 2 binning mode during DynaCT, which means the smallest high contrast object that can be resolved has a size of about 0.2 mm (Strobel et al., 2009).

Initially targeted at neuroendovascular imaging of contrast enhanced vascular structures, 3D C-arm imaging has been continuously improved over the years. It is now possible to acquire CT-like soft-tissue images directly in the hybrid OR (see Fig. 5). Beyond their use for trans-arterial catheter procedures, these 3D data sets are also valuable for guidance and optimization of percutaneous treatments. In combination with 2D fluoroscopic or radiographic imaging, information provided by DynaCT can be very valuable for therapy planning, guidance, and outcome control – in particular for complicated interventions (Doelken et al., 2008).

There are low-dose DynaCT protocols that achieve acceptable image quality for radiosensitive patients, such as pediatric patients, and provide adequate diagnostic image quality. In clinical practice, the balance between image quality and dose has to be considered. For the prerequisites mentioned above, a five second high contrast DR rotational 3D run applying 0.36 µGy/f can be reduced to 0.1 µGy/f resulting, in a dose saving of 72%. Low-dose DynaCT can be achieved with an effective dose of 0.3 mSv.

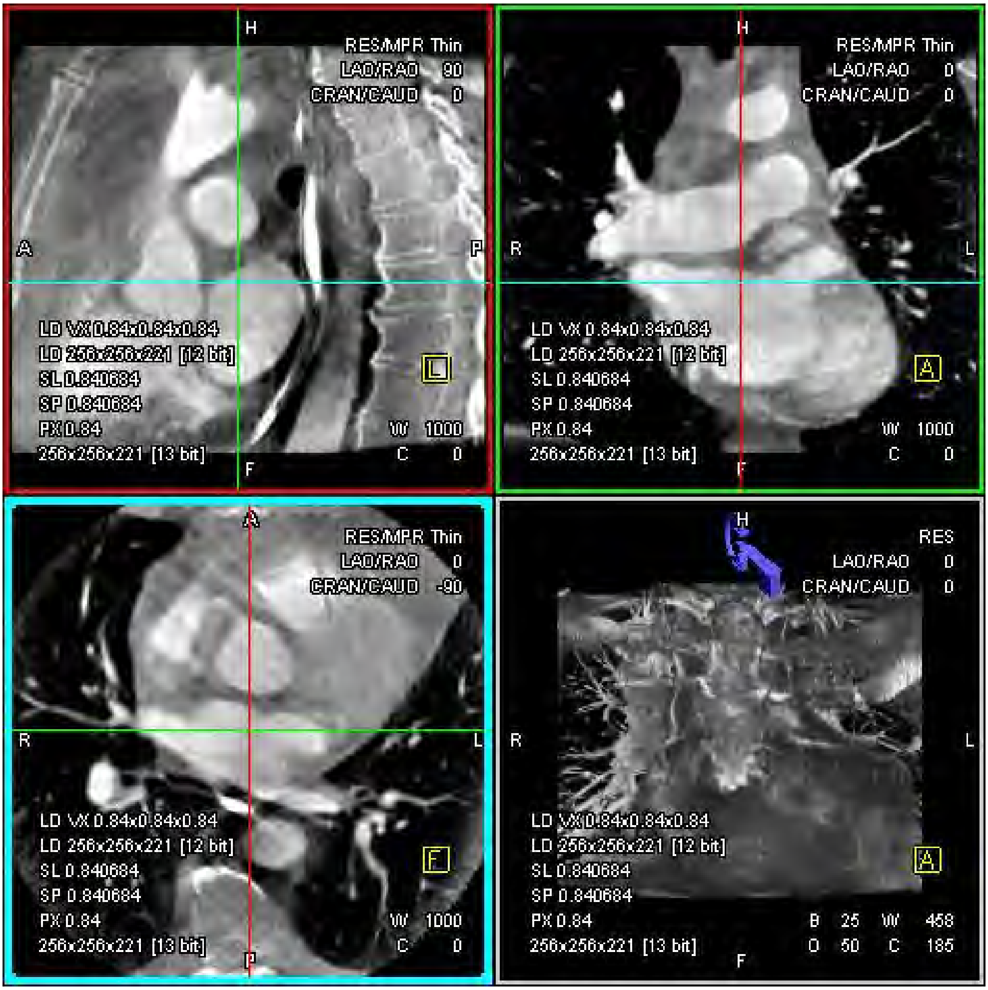

Fig. 5. Cardiac DynaCT image: the C-arm CT results were obtained with syngo DynaCT running on a syngo X-workplace (Siemens AG, Healthcare Sector, Forchheim, Germany)

3.6 Advanced visualization

Recent post-processing algorithms analyse an entire digital subtraction angiography (DSA) sequence at once and represent the sequence in one single colour-coded image. In order to obtain a colour-coded image, the algorithm takes the time to maximum opacification of each individual pixel, starting with the injection and subsequently visualising the distribution of the contrast medium through the vessels. These time measurements are then represented by a colour, allowing visualisation of the complete vessel tree in one image. Thus, the colours represent the contrast agent from its initial entry into the blood vessels to its flow throughout the anatomy of interest in one image.

Such dynamic flow evaluations provide a greater understanding of the contrast flow within the pathology, greater ease in visualizing the success of a procedure, and they assist the

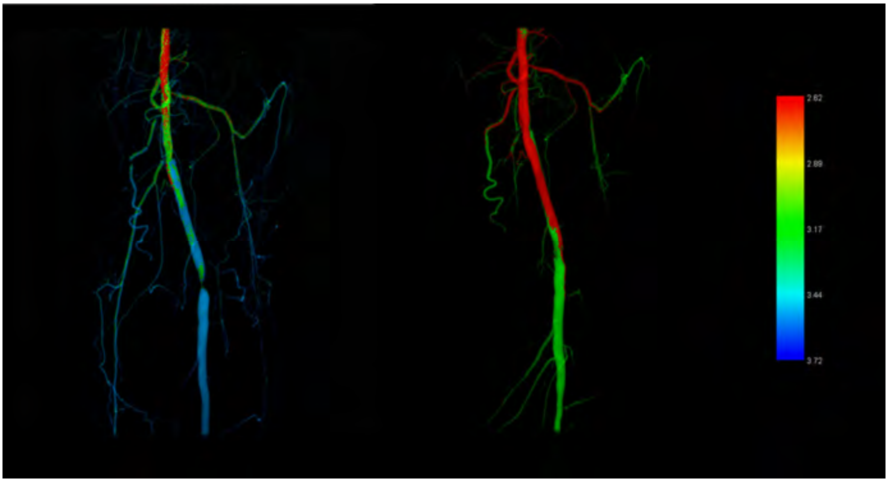

Fig. 6. Advanced visualization of an entire DSA sequence (iFlow): Colour-coded pre and post-procedural results visualize the improvement of flow

clinicians in image review by showing a complete Digital Subtraction Angiography (DSA) run in a single image (Ahmed et al., 2009). For example, this technology can be used to enhance pre-procedural and post-procedural imaging of patients under treatment for stenoses of peripheral vessels (see Fig. 6). Flow deviations and the increased utilisation of collaterals can more easily be detected prior to intervention, since anomalies more readily attract the physician's attention due to their specific colours. Following the intervention, the success of a balloon dilatation or stent implantation of a stenosis is readily visible due to the improved flow.

3.7 Fusion imaging and 2D/3D overlay

Modern angiographic systems are not just used for imaging, but support the surgeon also during the procedure by guiding the intervention based on 3D information acquired either pre-operatively or intra-operatively. Such guidance requires that the 3D information is registered to the patient. The next sections illustrate why 3D images acquired by an angiographic system are inherently registered with the patient and show new applications based on this fundamental feature of modern angiographic systems.

3.7.1 Information flow between workstation and angiographic system

3D DynaCT images are calculated from a set of projections acquired from different angles around the patient. The volume is reconstructed on a separate workstation. Even though the workstation and the angio system can be considered as separate systems, there is a close link and a continuous information flow between these systems. For example, when the user virtually rotates the volume on the workstation to view the anatomy from a certain perspective, the parameter of this view can be transmitted to the angio system, which then drives the C-arm to the exact same perspective for fluoroscopy. In the same way, if the C-arm angulation is changed, this angulation can be transmitted to the workstation which updates the volume to the same perspective as the fluoroscopic view (see Fig. 7).

The information flow between the angiographic system and the workstation ensures that an anatomical structure in the fluoroscopic image can be related to an anatomical structure in the 3D image and vice versa: that means the images are registered with each other. Even pre-operatively acquired images can be related to the patient by image-to-image registration of the pre-operative image with the intra-operative acquired DynaCT. Information in the pre-operative image (e.g. a surgical plan) can be directly overlaid on top of a live fluoroscopy.
Inherent registration of 3D images of the angiographic systems to the patient triggers new applications which go beyond just simple imaging, but towards image-driven guidance based on 3D information as illustrated in the next sections.

3.7.2 Overlay of 3D information on top of 2D fluoroscopy

Any 3D information extracted from the image in the workstation can be overlaid on the live fluoroscopic image. Firstly, the 3D image itself can be overlaid colour-coded on top of the fluoroscopic image. For example, in Fig. 8, a 3D angiography is colour-coded in orange and overlaid on the live fluoroscopy. Any change of the angulations of the C-arm will cause the workstation to re-calculate in real-time the view on the 3D image to match exactly the view of the live 2D fluoroscopy image. Without additional contrast agent injection the surgeon can observe device movements simultaneously with the 3D overlay of the vessel contours in the fluoroscopy image.
Fig. 7 illustrates an alternative way to add information from the workstation to the fluoroscopic image. After either manual or automatic segmentation of the anatomical structures of interest in the 3D image, the outline can be overlaid as a contour onto the fluoroscopic image. In this example, an AAA aneurysm has been segmented in the DynaCT image. The contour of the 3D segmentation is shown in the fluoroscopic view and provides additional information which is not visible in the fluoroscopic image. Overlaid landmarks do not necessarily need to be extracted from images directly, but might be added by the

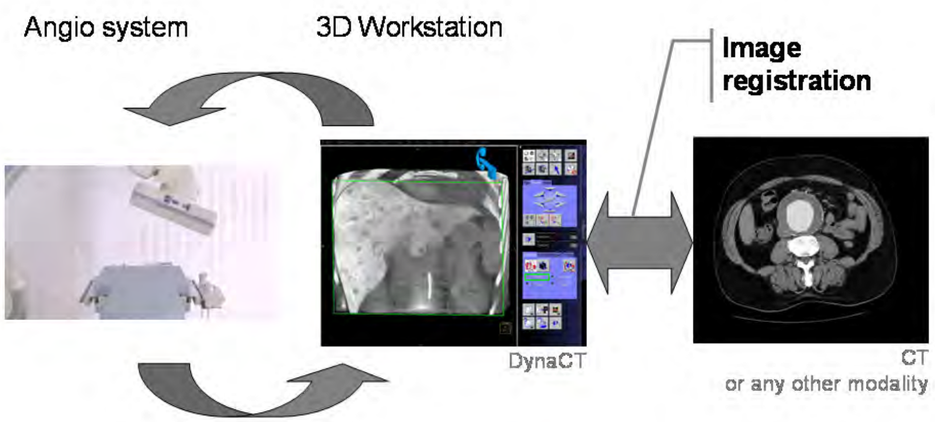

Fig. 7. Linkage between a modern angio system and its workstation. The corresponding information flow guarantees the registration between the 3D DynaCT image in the workstation and a 2D fluoroscopic live image and is the prerequisite of true 2D/3D image fusion

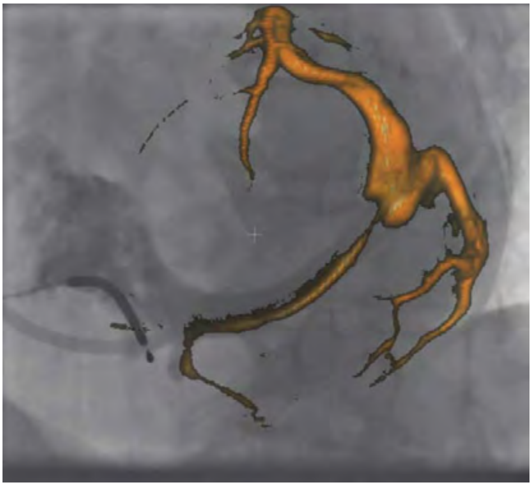

Fig. 8. Overlay of 3D DynaCT image (orange) on top of a fluoroscopic image during cardiac resynchronization therapy. Courtesy of K.-J. Gutleben, M.D., G. Nölker, M.D. A. Sinha, M.D., J. Brachmann, M.D., Department of Cardiology, Klinikum Coburg, Germany.

surgeon. For example to place fenestrated stents, a pre-operatively acquired CT image could be used to mark the ostia of the visceral arteries manually by the surgeon. By aligning the pre-operative CT image with the intra-operatively acquired DynaCT image, the ostia can be displayed (beside the contour of the arteries) in the fluoroscopic image. Notably, this truly is 3D information, i.e. any change in the C-arm position or angulations will update the view on the marks to perfectly match the live fluoroscopy image.

3.7.3 Guidance during Trans-Aortic Valve Implantation (TAVI)

Trans-Aortic Valve Implantation requires exact positioning of the valve in the aortic root to prevent complications. A good fluoroscopic view is essential, whereby an exact perpendicular angle to the aortic root is considered to be optimal for the implantation. Recently, applications have been released which support the surgeon in selecting this optimal fluoroscopy angulation or even drive the C-arm automatically into the perpendicular view to the aortic root (see Fig. 9).

Some approaches are based on pre-operative CT images, which are used to segment the aorta and calculate optimal viewing angles for valve implantations. CT images must be registered with DynaCT or fluoroscopic images to transfer the 3D volume to the actual angiographic system. Errors during the registration process might result in diversification from the optimal angulations of the C-arm and must be manually corrected. Additionally, anatomical variations between the acquisition of the pre-operatively CT image and surgery are not accounted for. Patients are generally imaged with hands-up in a CT scanner while surgery is performed with arms aside the patient, which leads to substantial errors.

Algorithms purely based on DynaCT images acquired in the OR by the angiographic system are inherently registered to the patient and show the present anatomy structures. With such an approach, the surgeon does not rely on pre-operative CT images acquired by the radiological department which simplifies the workflow in the OR and reduces errors in the process.

Fig. 9. Image-driven guidance during Trans-Aortic Valve Implantation (TAVI). Contours were automatically segmented from a 3D DynaCT image and the C-arm was positioned perpendicular to the aortic root for live fluroscopy based on anatomical landmarks extracted from the DynaCT image without user interaction. (Siemens AG, Forchheim, Germany)

4. Planning the hybrid room

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). Therefore, 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. Addiontional aspects for planning are material supply processes, i.e. of materials necessary for the procedure, and postoperative intensive care surveillance and treatment.

Due to high cost, OR facilities are commonly shared by different disciplines. 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 oftenly 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.

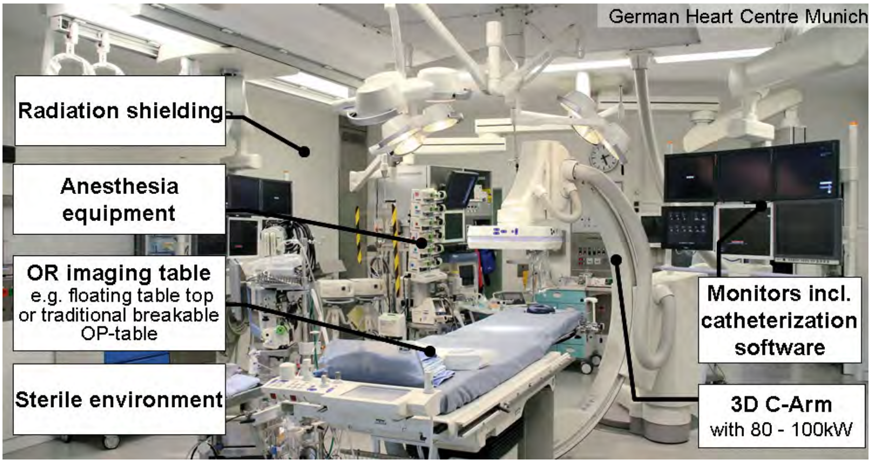

Fig. 10. Example of an hybrid OR highlighting relevant major equipment for planning

4.1 Team

Hybrid operating rooms are used by different surgical disciplines, interventionalists, cardiologists and anesthesiologists. Further staff working in these rooms includes nurses and technicians, resulting in a multitude of requirements impacting the room design and determining various resources like space, medical, and imaging equipment. Building a hybrid operating room needs a team approach with joint effort of customers and vendors (Tomaszewski, 2008; Benjamin, 2008).

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 endeavour.

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).

Team member	Topics
Surgeon(s)	Working positions, clinical applications, procedural descriptions, imaging and equipment requirements
Nursing staff (circulating and scrub nurses)	Working positions, patient and material logistics
Surgical technicians (i.e. perfusionist)	Working positions, equipment requirements
Anesthetist	Working positions, equipment requirements
Anesthesia nurses	Working positions, equipment requirements, material logistics
OR manager	Scheduling, general workflow management
Biomedical engineers	Technical room planning
Equipment planners, Architects	Technical room planning, construction, drawings, project management
Vendors	Installation requirements and schedule

Table 1. Team members of an OR and the issues they care about

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).

Fig. 11. Siemens robotic surgical C-Arm system Artis zeego

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 fibre 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.

Fig. 12. Example Siemens OR angiography table with a free floating tabletop

Fig. 13. Integrated Trumpf OR table with a radiolucent carbon fibre tabletop

Fig. 14. Integrated Trumpf OR table with breakable tabletop and metal parts that impair image quality

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.

For the surgical lights it is most important that they cover the complete area across the operating room table. Moreover, they must not interfere with head heights and collision paths of other equipment. The most frequent mounting position of OR-lights is centrally above the OR table. If a different position is chosen, the lights usually are swivelled in from an area outside the OR table. Because one central axis per light head is necessary, this may lead to at least two central axes and mounting points in order to ensure sufficient illumination of the surgical field. The movement range of the angiography system determines the positioning of the OR lights. Central axes must be outside of moving path and swivel range. This is especially important as devices have defined room height requirements that must be met. In this case, head clearance height for the OR-light may be an issue. This makes lights a critical item in the planning and design process (Tomaszewski, 2008).

Other aspects in the planning process of OR lights include avoidance of glare and reflections. Modern OR lights may have additional features, like build in camera and video capabilities. For the illumination of the wound area, a double-arm OR-light system is required. Sometimes even a third light may be required, in cases where more than one surgical activity takes place at the same time, e.g. vein stripping of the legs.

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 Heat, Ventilation, Air Conditioning (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.

Fig. 15. Example for a Laminar Airflow ceiling ensuring a clean environment above the surgical area

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.

Interventional rooms have excellent imaging capabilities, but frequently lack the prerequisites required for formal operating rooms. Operating rooms meet those required standards, but usually lack high-level imaging capabilities. Therefore, the hybrid operating room has different space requirements. The larger the better should be the basic principle for planning. Staff calculations have shown that, in hybrid procedures, up to 18 people are in the hybrid room. Current recommendations for hybrid operating rooms suggest > 70 m² in comparison to 40-60 m² 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

Centres with close proximity of intervention rooms and ORs probably have better prerequisites than hospitals with the classic separation of interventional rooms located in the internal medicine building and operating theatres located in the surgery building. In this situation, we recommend installing the hybrid room in the surgical wing for two reasons:

1. Immediate readiness of all OR equipment and personnel (e.g., heart-lung machine and perfusionists) and access to all surgical supply chain processes, especially in emergency situations
2. Availability of anesthesia and surgical intensive care

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

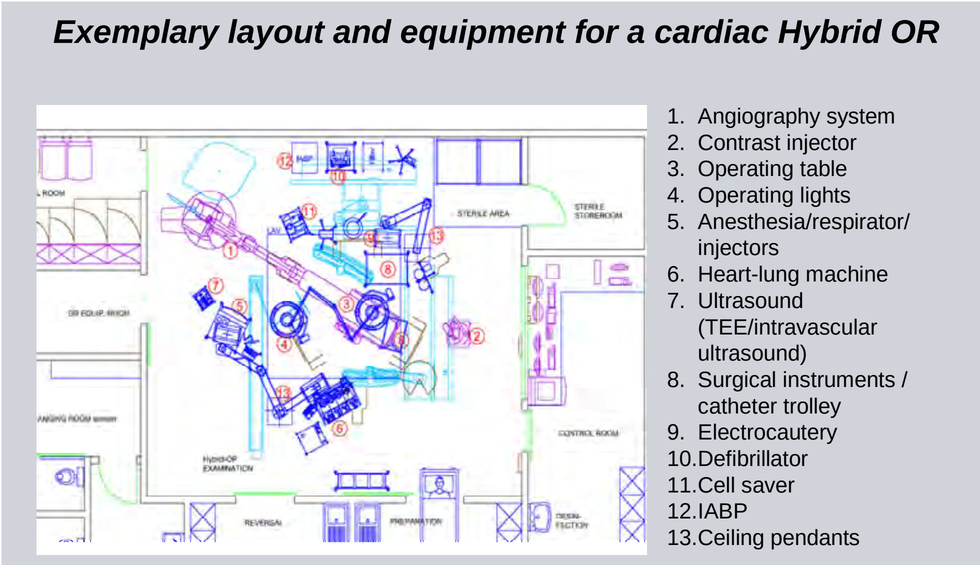

Fig. 16. A schematic room layout and equipment map of a hybrid OR depicts the complexity of planning an OR that allows for efficient workflow for all parties involved

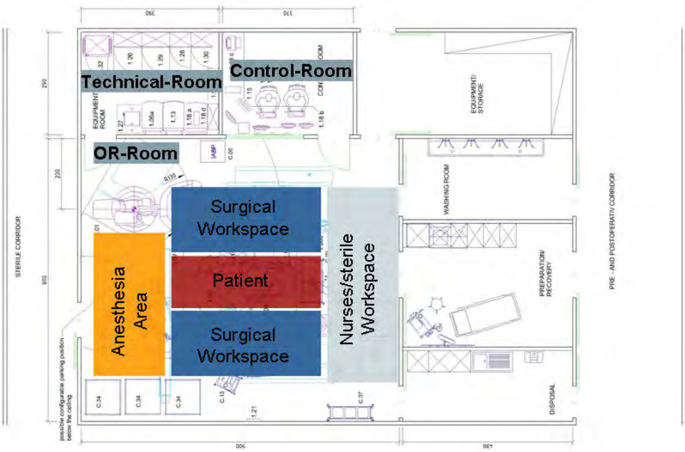

Fig. 17. Schematic Room layout with important areas for workflow considerations highlighted

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. Fig. 18 and Fig. 19 illustrate this issue.

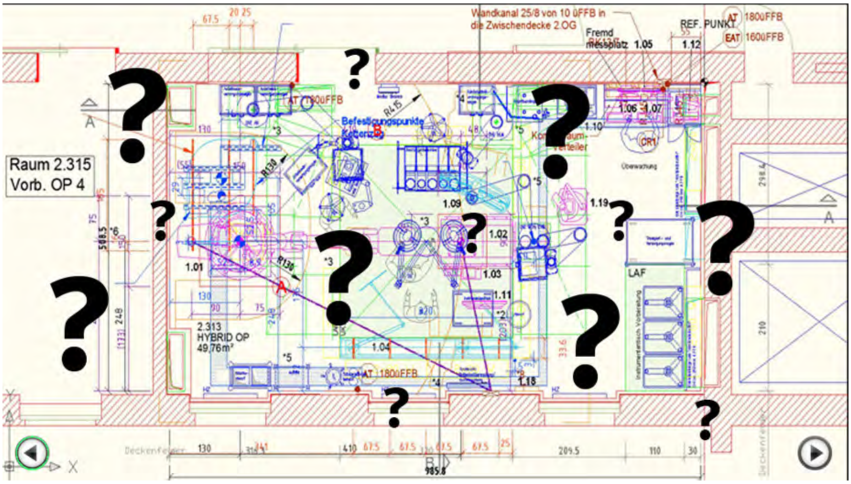

Fig. 18. Example for a 2D drawing of a hybrid OR plan capturing all interdependencies that has limited readability for the parties involved

Fig. 19. Examples for 3D presentation of a hybrid OR plan, ensuring a common vision of the future facility across all parties involved

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. The following checklist provides an overview of key aspects for consideration during the planning and design process:

Location and space requirements incl. ancillary spaces for technical room, storage, etc.	Workflow and standard room set-up
Cross-functional team	Angiography system
Surgical versus angiography table	Lights and illumination
Ceiling suspension units and services on these units (number of sockets, gases etc.)	Audio- and video integration including visualization and display placement
Mobile and other equipment, needs and position: anesthesia, monitoring and hemodynamics, injectors, ultrasound, heart and lung machine	IT-integration (HIS, PACS)

Table 2. Overview of key aspects to be considered during the planning and design process

5. Other considerations

5.1 Training for imaging

To take advantage of the multiple advanced imaging capabilities of state-of-the-art fixed angiography systems, extensive training for physicians, nurses and technicians is crucial. Most members of the OR team are not familiar with fixed angiography systems. Only if they are well versed in and comfortable using it, they can take full advantage of the imaging and workflow capabilities of a hybrid OR.

Training of the team can be achieved by different concepts. However, at least one member of the OR team should be trained in very detail in order to use the system to its full potential. This person should serve as a trainer for the other team members and should take responsibility for the imaging. A good possibility is to ask colleagues from the radiology department to take over the training of the OR team member, since they are very familiar with imaging. This specially trained team member should then train several super users, who are also very familiar with the system. By ensuring that multiple OR team members can operate the system very well, 24/7 coverage can be provided in the hybrid OR - also for emergency cases on weekends or during night shifts, if required.

The individual scope of training depends on the responsibility of the OR staff as well as on the workflow set-up. If for example the surgeon himself operates the angiography system, he will be among the ones undergoing training in system handling and operation. If, by contrast, the system is operated by a radiographer, the surgeon will not need to be trained in detail.

Training possibilities are multiple. Principle training may be achieved by training in the hospital's own hybrid OR by the provider of the imaging system (applications training), at other clinical sites by experienced physicians and technicians (mini fellowships), in other departments within the hospital, and at hands-on workshops, usually organized by the industry.

5.1.1 Applications training

When purchasing an angiography system for the hybrid OR, applications training is usually provided by the vendor of the imaging system. This training is generally intended for

experienced users and offered for approximately three days. Due to limited experience with imaging systems in the OR team, however, the training needs in surgery are much higher than for example in radiology.
Duration and content of the application training largely depend on how many different clinical disciplines use the system, on their level of experience and on the number of staff to be trained. During these trainings, the users are, depending on their scope of responsibility, being familiarized with system handling, software usage, image processing and archiving, the typical workflow in the hybrid OR and radiation protection. The trainers should be present during different clinical procedures in order to provide training and support system usage in clinical operation. Fig. 20a and Fig. 20b show an example plan for a three weeks applications training.

	Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**
a.m.	-System check **Training for surgeons/ anesthetists** -System and patient positioning depending on surgical request	**Training for surgeons** -System overview -Table/ C-arm -Foot switch -Exam set selection	**Training for nurses** -System overview -Table/ C-arm -Patient Registration -Exam set selection -Foot switch	**Examination** Pacemaker only	**Training for selected staff** -Workflow with 3D imaging -Patient transfer -Post processing at workstation -Archiving datasets
p.m.	**Training for OR nurses** -Collision risks -Sterile covering **Training for cleaning personnel** -System sterility	-Patient browser -Basic post processing -Modification of organ programs	-Patient browser -Post processing (Basic) -Archiving patients (Basic)	**Training for selected staff** -Post processing (Advanced) -Archiving patients (Advanced)	**Training for selected staff** -UPS -Emergency concept

Application support

Fig. 20a. Typical training schedule of the first week of application training for hybrid OR

5.1.2 Mini fellowships at clinical sites

Some experienced clinical sites also offer the possibility to do short fellowships. The fellow is being assigned to an experienced team for 3-5 days. During the fellowship the fellow will experience the typical workflow in a hybrid OR by accompanying the trainer through the different work steps, including treatment decisions and surgery, with the opportunity to discuss the workflow with the whole OR team.

5.1.3 Training in other departments within the hospital

It has also proven to be very beneficial to send a designated Super User to a department in the hospital that is very experienced with angiography systems, for example radiology or cardiology. An internship of about one week helps the user to become familiar with system usage under the guidance of experienced users.

	Day 1	Day 2	Day 3	Day 4	Day 5
a.m.	**Training for complete group** -Repetition of last week's training topics -Checking availability of necessary material	**Training for complete group** -Testing workflow with syngo DynaCT -Last adaptation -First 3D patient	**Training for complete group** -Performing -*syngo* DynaCT -Last adaptations -Second 3D patient	**Training for complete group** -Third 3D patient	**Training for complete group** -Forth 3D patient
p.m.	**Training for complete group** -Performing *syngo* DynaCT run -Testing and improving workflows and positions	**Training for complete group** -Performance check	**Training for complete group** -Performance check	**Training for complete group** -Performance check or -Next Patient	

Application support — Customer's responsibility

Fig. 20b. Typical training schedule of the second and third week of applications training in the hybrid OR

5.1.4 Hands-on workshops

Some device and imaging vendors offer hands-on trainings at conferences or in their factories or showrooms for physicians that are just starting to use imaging systems. During these trainings, experienced cardiac surgeons and cardiologists train less experienced surgeons and fellows on transcatheter procedures and imaging. Corner stone of these trainings are the hands-on sessions. The trainee is guided by an experienced cardiologist or surgeon while practicing the use of devices like catheters and valves under real image guidance by an angiography system. The system and room set-up resembles a real hybrid OR or hybrid cathlab (see Fig. 21).

Fig. 21. An experienced interventional cardiologist teaches surgeons in basic wire techniques.

5.2 Financial considerations

Building a hybrid operating room is a considerable economic investment for every hospital. Sound business models and optimal usage of the room are prerequisites to make this endeavour a financial success.

5.2.1 Costs

The costs for hybrid rooms vary considerably depending on whether or not re- or new construction is necessary.

Furthermore, it may be necessary to hire additional staff such as radiology technicians that are familiar with interventional imaging systems. Both new and existing staff may require outside training to be able to use the equipment properly. These decisions depend on the existing knowledge in the hospital and on what procedures will be performed.

A recent study (Neumann, 2009) compared the investment necessary for hybrid suites, cath labs and standard ORs. Room size, construction requirements, angiography system, other equipment, depreciation, maintenance and debt service were taken into account. Overall, investment costs for the standard OR were lowest, followed by the cath lab with a 25% higher price tag. The costs for a hybrid OR were additional 120% of the costs of the standard OR. When comparing the operating costs (maintenance, depreciation, debt service and rent) the same relations applied. The costs for the cath lab were 25% higher than for the OR. Comparing the OR with the hybrid OR, an additional 90% were required per annum.

These figures may differ, depending on system choice, building costs and local requirements but the above mentioned figures give a good indication on the comparative costs. Taking these reasonably high costs into account, the obvious question arises how a hybrid OR can be a profitable investment.

5.2.2 Return on investment

Several US hospitals reported in detail on return on investment. The Vanderbilt group (Greelish, 2009) focused on the growth of a cardiac surgery program through a hybrid room. In the year 2004 the annual case volume of adult cardiac cases was 464. 2004 was also the year when the institution built their first hybrid OR. In the next 3 years the case load almost tripled based upon the hybrid OR set-up.

A similar case load development as in Vanderbilt Heart is to be seen in Beijing's Fu Wai Hospital. The annual report 2008 shows an increase of over 60% of the hybrid procedures a year after their hybrid OR was installed (Fu Wai, 2008).

In an initial pro forma from St. Vincent Heart Center of Indiana (Cronin & Schroyer, 2010) the calculations showed that incremental discharges of 150 patients led to a gross patient revenue of $ 6.2m and net patient revenue of $ 2.4m. Deducting total expenses of $ 0.8, the excess of revenues over expenses was $ 1.6m. The net present value was calculated to be $ 0.8m in 2010 and $ 5.4m in 2015, leading to an internal rate of return of 185% in 2010 and 285% in 2015, respectively.

Data from Cleveland Clinic Foundation showed the return on investment of their cardiac hybrid OR to take only 2 years and 3 months (Cronin & Schroyer, 2010).

The Advisory Board Company reported a detailed investment calculation for a room focusing solely on TAVI procedures in the USA (Katz, 2010). In reality the wide majority of rooms will be used for a multitude of procedures, often from different surgical disciplines in order to make best use of the room capacity. In the Advisory Board Company's pro forma, focussing only on TAVI cases, the cumulated investment came up to $ 3.4m, consisting of $

1.3m for construction work and $ 2.1 for the equipment. In the first year, starting with a very low volume of TAVI patients of 24 and consequently lower revenue of $ 1m, the total net revenue was $ 0.9m after reducing bad debt allowance and billing & collection. Annual total fixed costs accumulated to $ 0.1m, variable costs for devices, labour etc. to $ 0.9m leading to total costs of $ 1m during year one. Consequently the net income was negative by $ 23k in the first year. With an increase in patient volume to 37, however, already in year two a net income of $ 0.4m could be realized.
Table 3 gives an overview and comparison of the cost and return situation (by St. Vincent Heart Center and the Advisory Board Company).

	St. Vincent Heart Center	Advisory Board Company
Gross patient revenue in year 2010 (St. Vincent) / year 1 (Advisory Board)	6200	1000
Net revenue	2400	900
Total expenses	800	1000
Net Present Value (NPV) in year 2010 (St. Vincent) / year 1 (Advisory Board)	800	-23
Net Present Value (NPV) in year 2015 (St. Vincent) / year 5 (Advisory Board)	5400	1300

Rounded figures in k USD

Table 3. Financial comparison of pro forma from St. Vincent Heart Center and The Advisory Board Company (Cronin & Schroyer, 2010)

As a general fact, the set-up of hybrid rooms allows for the treatment of previously untreatable patients. Good examples are TAVIs. Now, patients previously deemed too old or weak for surgery, can be treated by transcatheter valve implantation. With an aging population and developments in medicine, the number of octogenarians and nonagenarians to be treated with new hybrid and minimally invasive procedures that are best performed in a hybrid OR will continue to grow. This will lead to increasing usage of the room capacity and consequently a quicker return on investment. Also, with less invasive treatment the necessity to stay in the ICU and the hospital for a long time in general decreases, along with the risk of infections. This allows discharging patients quicker, which again leads to an improved cost situation in the hospital. Furthermore hybrid rooms help to increase efficiency and decrease turnover time which can lead to additional cases being performed in the hybrid room as compared to a standard OR (Benjamin, 2008). A conventional surgical valve replacement often takes more than three hours, whereas a transcatheter valve implantation can be done in one. Calculations indicate that the mean incremental operating room profit per procedure is about $ 1,500 per hour. If the hospital manages to add only one single hour-long case each day, the hybrid OR could help increase profitability by about $ 300k p.a.
In cardiac surgery, the operating room profit is usually even about 25-30% above the mean incremental OR profit (Resnick et al., 2005).

5.2.3 Positive marketing effects

Another soft factor that can have a positive financial impact is to use the hybrid OR to position the hospital among the technologically most advanced institutions in the area. This

helps to both attract the top medical staff to work in the hospital as well as additional patients that are searching for the best possible treatment.
Also many hospitals make use of the increased publicity they can gain by marketing their hybrid ORs for the public e.g. in TV reports (see Fig. 22).
In summary, to justify the substantial investment in the hospital a detailed business plan needs to be created, taking into account the specific situation in the hospital. Hospital administration usually accepts a start-up phase with a negative margin but will expect positive numbers after. A detailed business plan will enable both users and hospital administration to base the decision for the hybrid OR on solid grounds and make sure it will be used to its full potential.

5.3 Building a hybrid program

One key success factor for a hybrid operating room is the team approach of a committed interdisciplinary team that takes responsibility for the room. Imaging specialists, cross trained physicians, and nurses with the vision to establish new minimally invasive therapies are the cornerstones of a blooming hybrid therapy program.
Bonatti stresses the importance of a dedicated workflow coordinator (Bonatti et al., 2007) to direct the workflow. Since the workflow in a hybrid OR has major differences to the one in a conventional OR it is mandatory that the whole OR team approaches the new concept open-mindedly and willing to change traditional processes fundamentally.
The workflow coordinator or hybrid OR manager takes care of traditional OR management topics such as staffing, ancillary support and inventory management. But he also manages some new tasks such as prioritizing the cases as in giving true hybrid cases priority over standard surgical or cardiologic procedures that can be done in a normal OR or cathlab. He

Fig. 22. Coverage on tv.berlin about the hybrid OR at German Heart Center Berlin, Germany

also needs to assure that cross trained physicians are available to work in the new room (Katz, 2010).
A multi-disciplinary 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).
However, not only operational integration is necessary, but also financial integration. Accounting practice needs to change with the usage of a hybrid OR. To start with, some institutions split the charges for hybrid procedures into a percutaneous component performed by the interventionist and billed by the cathlab, as well as a surgical component executed by the surgeon and billed by the OR department (Katz, 2010).
Moving forward, full financial integration is of utmost importance in order to avoid competition between different clinical disciplines. Consequently, all involved cardiovascular departments should be under one profit and loss statement of an integrated cardiovascular center (Katz, 2010).
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 of major help in the planning process. Learning from their experience and understanding their mistakes can help shorten the process for all involved staff considerably.

6. References

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