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White Paper

The Trauma Surgeon

The Hybrid Operating Room Center for Intraoperative Imaging

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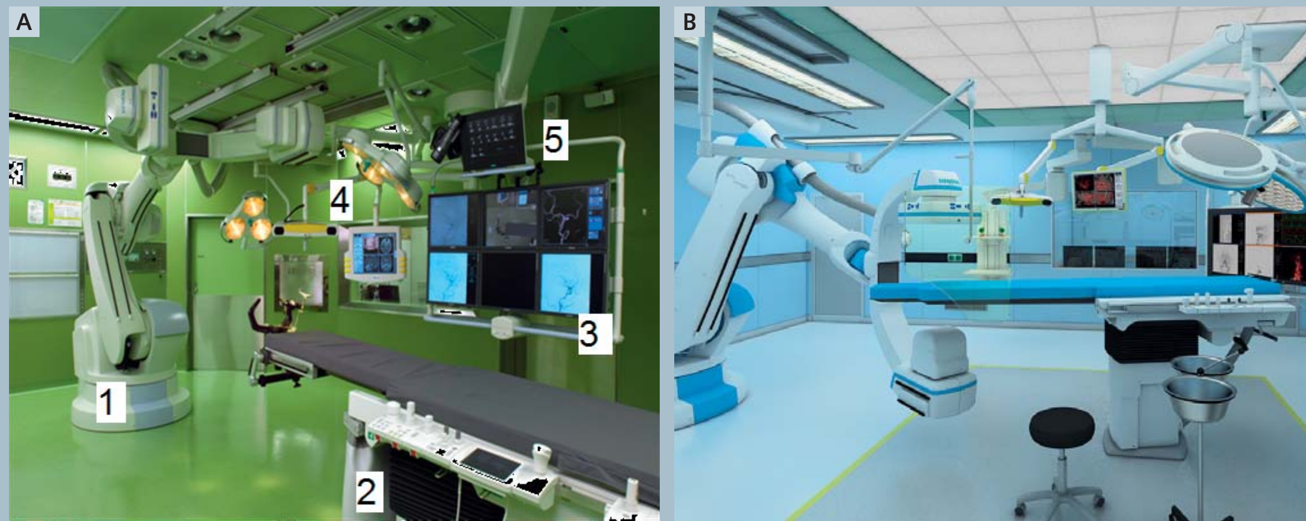

Fig. 1

The Hybrid Operating Room

Center for Intraoperative Imaging

Since its introduction just 60 years ago, intraoperative imaging has been constantly evolving. Over recent years, the trend is moving from simple two-dimensional image intensifiers to motorized C-arms that can generate CT-like data sets in the operating room (OR), therefore placing a new control instrument in the hands of surgeons.

A new era in the use of modern imaging processes and their integration with other essential components of the OR is on the horizon. The combination of modern flat detectors, industrial robots and modern OR table technology with a navigation system has greatly expanded the range of uses and broken through old barriers.

Image intensifiers have been in use for immediate intraoperative visualization since the 1960s. Various specialized medical disciplines make use of this technology. In addition to their use in trauma and orthopedic surgery, e.g. fracture repair and spinal surgery, intraoperatively acquired images are used in neurosurgery, cardiology, vascular surgery, and oral and maxillofacial surgery.

The introduction of motorized systems able to produce three-dimensional (3D), CT-like image data sets launched a revolution in intraoperative imaging.

These angio image intensifiers were initially used in cardiac and vascular surgery and have made increasingly deeper inroads into the trauma OR [16] since the end of the 1990s.

Hybrid OR – What exactly is it?

The term hybrid OR describes a workplace where a variety of interventional and surgical procedures can be performed. It does away with the traditionally strict separation between medical specialties in the OR. A hybrid OR has to be set up to fully meet the requirements of each and every department that uses it. In addition to open surgeries, minimally invasive procedures also need to be accommodated. This places particular demands on the technology being used. Fig. 1 shows two possible floor plans for configuring a hybrid OR.

Technical Prerequisites

There is no standard prescription for how a hybrid OR should be set up. But certain technical prerequisites must be met in order to meet all needs. Essential to the OR is the networking of all the required devices, like the OR table, the imaging unit, the hospital information system and the navigation instruments. Table 1 provides an overview of the required and optional technical installations.

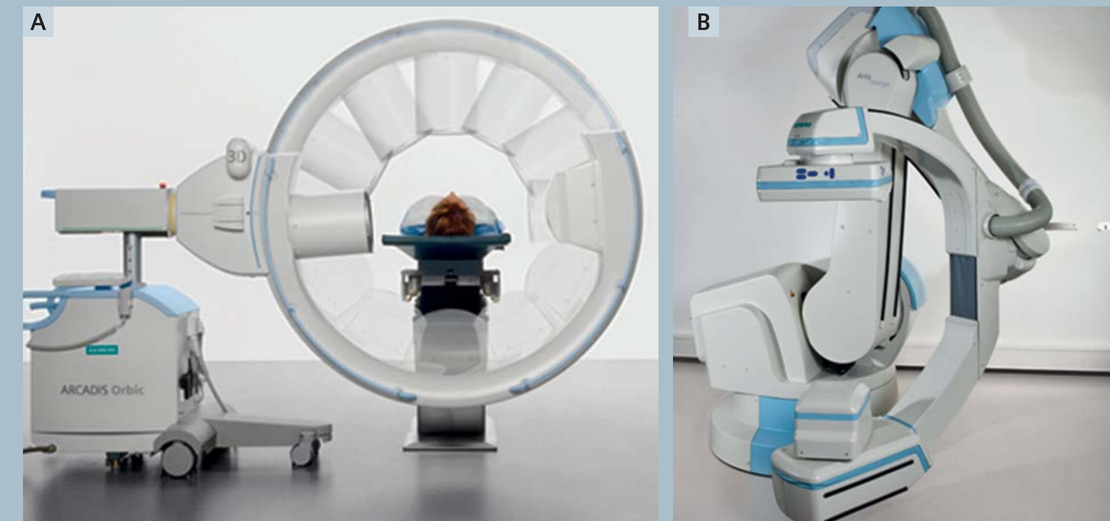

Fig. 2

Imaging

In principle, there are two different installation options available: mobile and fixed systems. Choosing one largely depends on the layout of the room. The main advantage of mobile systems is that they can be used in other rooms (Fig. 2a). The major disadvantage compared to stationary systems is their low tube performance (2–25 kW vs. the recommended 80–100 kW) and low frame rate (25 f/s 50 Hz vs. the recommended 30 f/s 50 Hz). This is especially true in cardiac and complex vascular interventions that visualize fine wires in central vessels of the body, where such systems can fall short [6] (Siemens Arcadis avantic is an example of a mobile C-arm providing the required 30f/s 50Hz). Another limitation of some of the mobile systems is overheating during complex and long interventions due to lower cooling capacity compared to their permanently installed counterparts.

Fixed systems can be installed on the ceiling or floor. Hygiene requirements need special consideration with ceiling-mounted systems since highly mobile components directly above the surgical site can compromise sterility in hybrid ORs, which are also designed for open interventions. Laminar ventilation units also suffer. Yet their advantage lies in their extreme flexibility of movement, often making repositioning the OR table superfluous. For 3D applications, the scan can also be done from both sides of the patient. The rigid floor column of floor-mounted units often do not allow this. Table movements are also needed more frequently and one side of the OR is partially taken up by the equipment. The floor-mounted C-arm, however, is easier to put in the park position without colliding with the remaining ceiling-mounted equipment. The third and latest configuration is the C-arm on a robotic arm, which automatically moves to the table from its neutral position and is connected with the OR table to avoid collisions (Fig. 2b). This type of C-arm is as flexible as ceiling-mounted systems, even though it is mounted on the floor. Mounting the arm on an industrial robot results in the improved range of travel. Another key advantage is operability by the surgeon. New image intensifier should be replaced by detection systems.

Typical technical equipment	Optional equipment
Imaging unit	Navigation module
Surgical table	Endoscopy unit
Anesthesiology workplace	Defibrillator
Instrument table	Cell saver
Ventilation equipment	Mobile monitor systems with PACS connection

Table 1: Overview of typical and optional equipment in a hybrid OR

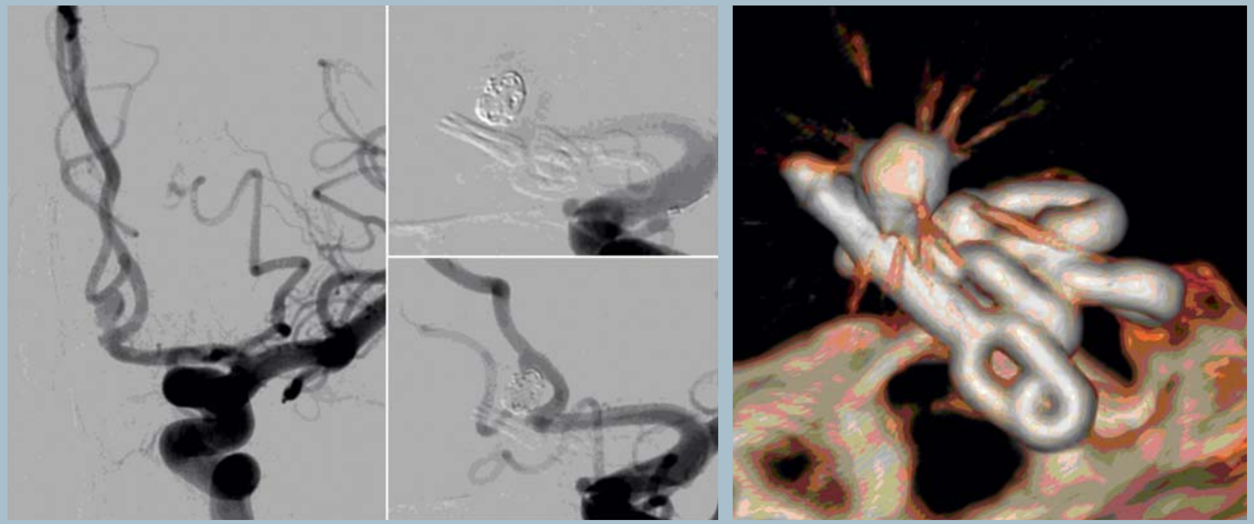

Fig. 3

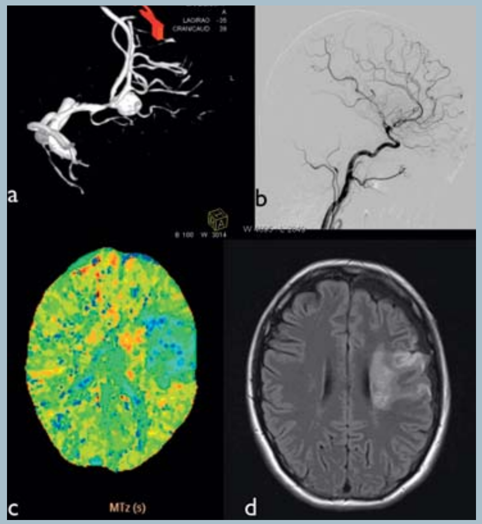

Fig. 4

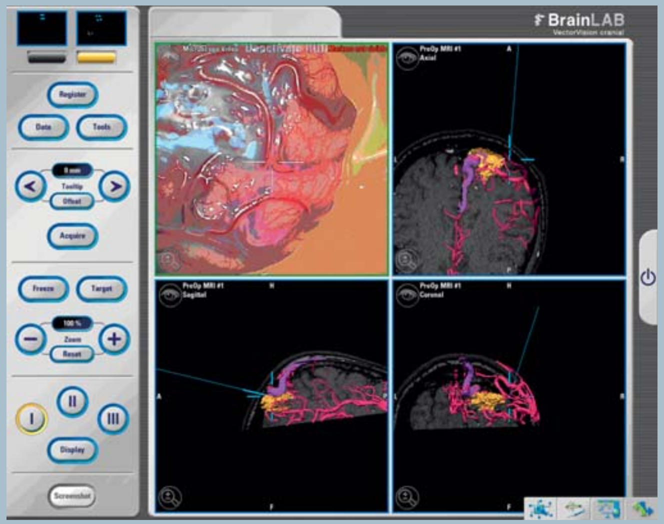

Fig. 5

3D Imaging is a Must in the Modern Hybrid OR

All the above systems can meet this requirement. Using a robotic system saves valuable time during a 3D scan since the image acquisition speed of these systems far exceeds all the others cited.

OR Table

Modern OR tables offer a variety of configuration options and are designed for widely differing applications. Tables used in the hybrid OR, however, must meet special requirements. Since intraoperative imaging is at the heart of interventional and surgical procedures, especially in this OR, the table needs to support not only conventional interventions, but be integrated such that artifacts are kept to a minimum. Because the room is used by many disciplines with a wide range of patient positioning needs, the table must guarantee the highest level of flexibility. Modular OR tables offer the most flexibility and are therefore perfect for use in the hybrid OR. Parts of the table can be manufactured from carbon to reduce artifacts.

OR tables come in mobile and permanently installed models as well. A permanently installed table best meets the needs for combining and integrating all the components of the OR. Linking the imaging unit to the control of the OR table ensures safe and time-efficient image acquisition.

Computer Navigation

Computer navigation systems have been studied for specific neurosurgical interventions, in particular tumor, cardiac and maxillofacial surgery, orthopedics and trauma. These systems can support surgeons in a number of ways [1, 10, 15, 17]. Setup time was a major disadvantage with older navigation solutions, which often consisted of a separate camera, a workstation with monitors, and a dedicated C-arm [2]. For every operation, they had to be specially set up in the given OR, networked and then powered up. In a hybrid OR equipped with a navigation system, no lengthy setup procedures are required. The camera systems can be permanently installed on the wall or the ceiling and even a mobile camera can be integrated. In new installations, the additional trolley with the workstation and monitor unit of the actual system can be housed in a separate, central computer room, thus saving valuable OR space. Another advantage is the lack of cabling, which in today's OR often winds through the entire room once all the systems are connected, representing a safety hazard.

Other Technical Requirements

One key benefit to this type of surgical unit is how easy it is for the surgeon to control and operate the above components. All the required computers can be housed in a separate control room to keep the OR clear of excessive technology. Different manufacturers offer integrative control solutions that e.g. can be operated from a central monitor. This can be installed on the wall or the ceiling to gain the utmost flexibility for every imaginable application. Even images from the hospital PACS (picture archiving and communication system) or pre-operative planning can be displayed there.

Due to the optimized control of the C-arm, which is also connected to the OR table and hence virtually collision-free, the surgeon can determine the position of the image acquisition without calling on the assistance of technical or nursing personnel. The optimal settings are stored in the system and can be restored at the touch of a button. Others in the OR (e.g. assistants) can view the system images or even endoscopy images on a second monitor system without moving from their ideal working position. Recordings can also be transmitted and saved for documentation or teaching purposes.

Uses in Neurosurgery

The value of intraoperative angiography in neurovascular interventions seems clear:

- Cerebral aneurysms: in 5–7.3% of aneurysm operations (clipping, Fig. 3) the aneurysm may not fully close off, with subsequent risk of persistent bleeding. In 3–9% of cases the artery with the aneurysm or one of its branches occludes (Fig. 4), resulting in stroke [18].
- Cerebral arteriovenous malformations (AVM): Although AVMs are resectable, in up to 15% of cases undetected residue may remain, which can increase the patient's risk of hemorrhage over allowing the condition to run its natural course.

Even though intraoperative angiography is obviously advantageous, it has not made inroads into most neurosurgical clinics because there were no designated DSA systems available in most neurosurgical ORs. Use of angiography-capable C-arms did prove to be greatly lacking: poor image quality, low resolution, no 3D image [7].

By implementing the concept of a central, interdisciplinary hybrid OR, a unique technology can be used, especially in the treatment of neurovascular diseases. A 3D-capable C-arm can be used to examine the perfusion of the brain tissue and the blood flow relationships in complex neurovascular pathologies. A hybrid OR, connected to a modern navigation system, automated data management and patient registration, offers considerable advantages, especially in navigation-assisted neurovascular interventions (Fig. 5). Furthermore the hybrid OR allows patients with complex vascular diseases to be treated in a single intervention, combining microsurgical and endovascular methods [14].

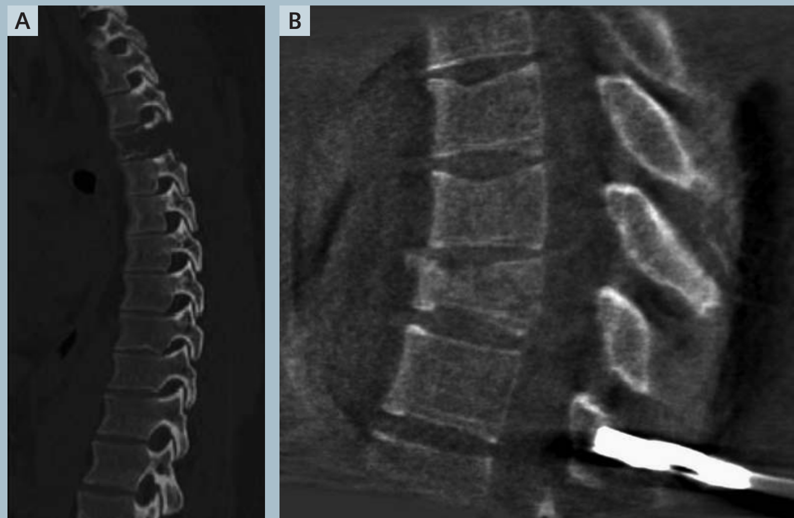

Fig. 6

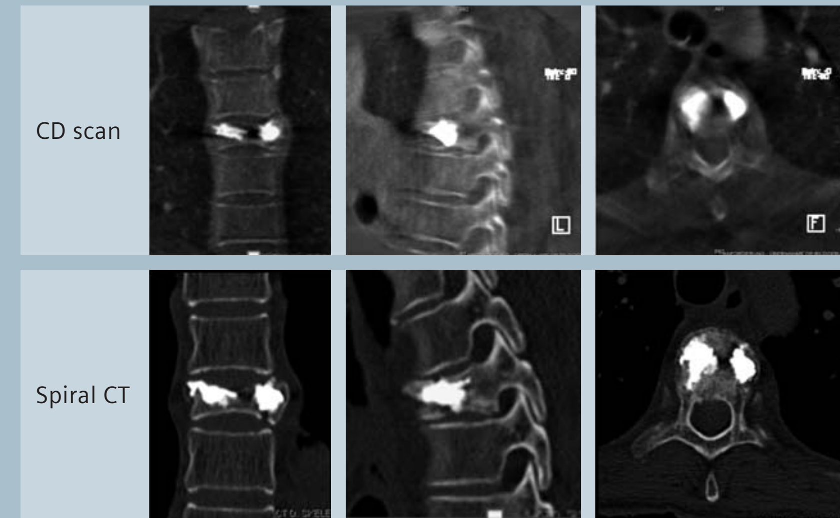

Fig. 7

Uses in Orthopedics and Trauma Surgery

Navigation-guided Pelvic Surgery

Because the robotic-supported 3D imaging results in a substantially larger ROI, the full human pelvis can be visualized including surrounding soft tissues. For the first time, this makes it possible to use navigation-guided procedures for a complex pelvic injury with the involvement of multiple pelvic structures. The current use of navigation-guided procedures in this field is focused on inserting a screw via the sacroiliac joint for instability of the posterior pelvic ring [2, 20]. Navigation support can substantially broaden this limited application in the future.

Introducing navigation procedures in pelvic surgery can further the trend toward minimally invasive techniques including the anatomically complex pelvic region.
After the initial scan is taken, other imaging steps can always be integrated as needed to increase surgical safety and minimize complications. Furthermore, integrative applications permit incorporating preoperative images, e.g. through image fusion, to further enhance the image quality intraoperatively.

Complex Spinal Surgery

For the first time, the visualized volume permits longer spinal segments to be displayed in one data set (Fig. 6).

This opens up new possibilities, especially in cases of multiple fractures or lesions near the cervical and thoracic spine. The small image volume of other systems often made it possible to perform navigated stabilization on only a single vertebra. Other scans were needed for additional vertebra, taking even more time and doubling the radiation dose.

Improved intraoperative imaging enables optimized post-operative control in spinal surgery. Besides being able to check the position of the pedicle screw, the surgeon is also able to generate CT-like images post-kyphoplasty. The improved image quality can also be expected to expand neurosurgical applications, e.g. minimally invasive decompression surgery [3].

Navigation-assisted Tumor Resection

In orthopedic and trauma surgery, there is currently a substantial gap when it comes to preoperative imaging during tumor staging and intraoperative imaging capabilities during tumor resection. The size and extent of the tumor can be defined both in the bone and the soft-tissue window in computed tomography (CT) or magnetic resonance tomography (MRT). PET-CT procedures (positron emission tomography – computed tomography) enable precise correlation between soft-tissue parts and the tumor's spread into bone. These images, however, could not be used intraoperatively for navigation purposes until now, much less be generated in the OR itself.

New, high-powered systems permit image fusion on the fly, in the OR or in a networked system. Besides saving considerable planning and preparation time, the surgeon can now use navigation solutions to constantly ensure adherence to preoperatively defined resection margins.

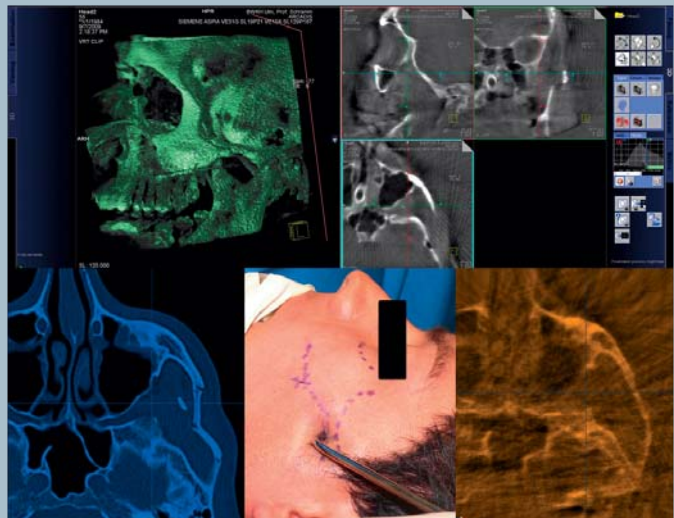

Fig. 8

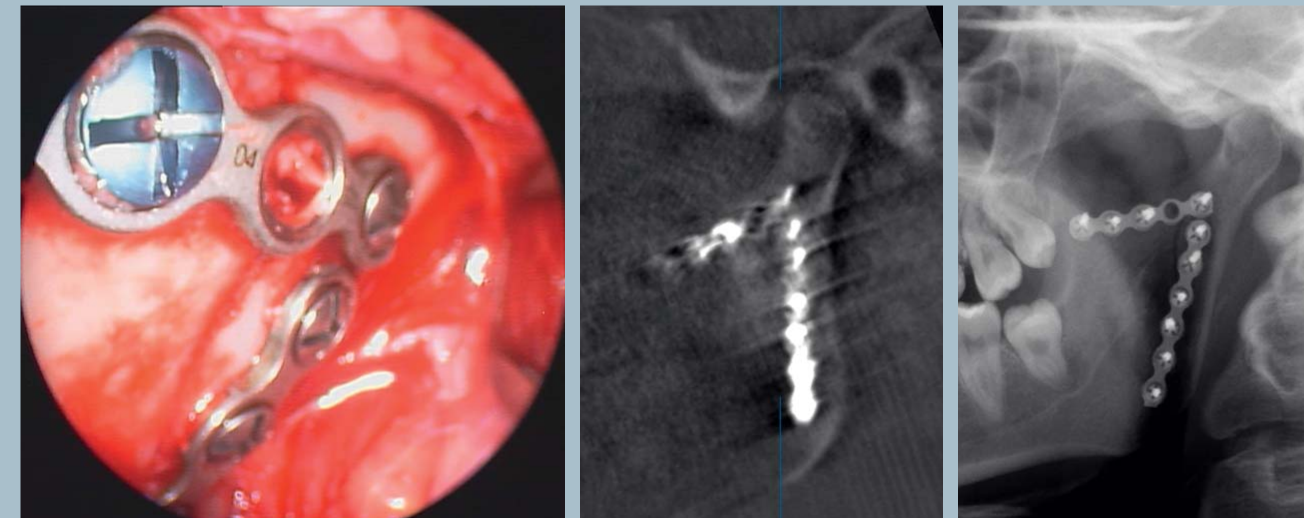

Fig. 9

Applications in Oral and Maxillofacial Surgery

Minimally Invasive Procedures and Biopsies

Navigation-supported biopsies were the first applications of computer-assisted surgery in the head and neck region. In the meantime, they are now widespread and are considered as the domain of frameless stereotaxis. For relapse excisions and tumor monitoring after performing adjuvant radiation therapy, a purely visual orientation at the surgical site is often inadequate due to anatomy changes.

The advantage of intraoperative navigation in these cases lies in the combination of pointer-based, endoscopy-supported treatment and microscopic treatment. The access path and the target vital structures can be marked preoperatively and visualized intraoperatively. Indications for use of navigation-assisted surgery include biopsies in sites previously operated on or treated, multiple biopsies requiring objectively verifiable mapping of the biopsy specimen and the extraction point, and the decompression of the optic nerve.

Primary Reconstruction of the Facial Skull

During surgical reduction and osteosynthesis of fractures of the facial cranium, time to collect data sets is brief. Intraoperative imaging with a C-arm with 3D capabilities (intraoperative volume tomography) can therefore be used for positioning control before sutures are closed as well as in the clinical routine. In lateral mid-face fractures, incorrect positioning of the cheekbone and zygomatic arch can be avoided, especially in minimally invasive, transcutaneous traction-hook reductions (Fig. 8). Intraoperative imaging after reduction of the zygomatic arch eliminates unnecessary orbital explorations in cases where the orbital floor is involved. This also avoids second surgeries due to inadequate reduction, e.g. after intraoral endoscopy-assisted treatments of condylar process fractures (Fig. 9).

The immediate treatment of facial cranium fractures, especially with involvement of the nasoorbitoethmoid complex, is superior to secondary care in terms of functional recovery and should therefore be the primary treatment objective [9]. The limited access to the periorbital region, however, makes intraoperative visualization necessary so the surgeon can check the intermediate steps of the reconstructive procedure and thus be able to perform the interdependent partial reconstructions with utmost precision. Intraoperative CT allows for intraoperative visualization. Intraoperative navigation enables intraoperative positioning control during reconstruction of the eye sockets and mid-face completely without radiation and without interrupting the intervention. Precisely detailed, direct or indirect visualization of the bony and, if necessary, even the soft-tissue structures is possible at every phase during the operation (Fig. 10). Delayed immediate treatment is usually the rule for isolated fractures of the orbital walls (medial wall or orbital floor) since these fractures are often not obvious to the examiner during initial care, overlooked due to lack of functional restrictions (double vision, sensory disturbances in the area innervated by the infraorbital nerve), or the need for treatment underestimated. Especially in cases of orbital wall fracture with involvement of the junction of the orbital floor to the medial wall or complete blowout of the orbital floor, the limited view offered by the favored transconjunctival access is often the reason reconstruction materials are positioned incorrectly.

Delayed immediate treatment is usually the rule for isolated fractures of the orbital walls.

Due to accompanying soft-tissue changes and central compensatory processes, a required secondary correction is decidedly inferior compared to anatomically correct primary reconstruction (double vision is compensated for in the visual cortex and can persist after secondary corrections). Intraoperative visualization is therefore required in these fracture patterns to avoid this type of incorrect position and considerably reduce the number of required secondary reconstructions. Alloplastic materials such as titanium mesh will increasingly supplant the use of autologous bone transplants because of better predictability and absence of extraction morbidity. In extensive shattering of the facial cranium, voxel-based data processing produces a clear picture of the fracture pattern in 2D and 3D. For bilateral or central shattering or malformations, free segmentations to simulate ideal reconstruction are needed. With voxel-based planning and intraoperative navigation, there is no need for a coronal incision even in extensive orbital wall and panfacial fractures if the nasoorbitoethmoid complex is not fractured multiple times or the medial lid angle does not need refixation.

Fig. 10

Fig. 11

For complex orbital wall fractures, the CT data set is autosegmented into anatomical and surgical units. Then, by freely shaping the segments (bilateral fractures) or mirroring the unaffected opposite side (unilateral fractures) with subsequent orientation of the segmentation, a virtual mold can be created for orbital reconstruction. Precontoured titanium implants can be virtually inserted preoperatively and their fit checked. The dimensions of these implants were determined from hundreds of CT data sets of unchanged orbital and periorbital regions [12].

The navigation system is initially referenced either with the maxillary splint or using the preoperatively inserted calvarium screws. To ensure uninterrupted surgery, the splint is then removed and reinserted only for intraoperative referencing. Re-referencing should be performed after all manipulations with a high degree of motion of the surgical site, such as osteotomies or extractions of bone transplants from the calvarium.

The overall duration for referencing during these interventions (1–3x per intervention) is between 5–15 min. on average. Pointer-based navigation post-referencing includes checking the position of the cheek prominence and surface after reduction and before osteosynthesis, as well as surface matching of the inserted titanium mesh and/or bone transplant in the sockets prior to fixation. Pointer-based navigation also assists in determining the projection of the eyeball for drawing conclusions on swelling behavior and expected sagittal projection of the eyeball on bilateral comparison.

After transconjunctival insertion of the titanium mesh, the position is checked using intraoperative navigation. The tip of the pointer lies on the inserted titanium mesh and the position of the tip in relation to the virtually reconstructed mold indicates the current position of the mesh. This way the position and the fit of the implant can be checked intraoperatively and changed as often as necessary. Then the 3D C-arm is used for intraoperative imaging. By fusing the data set with the preoperative data set and the preoperative simulation, the result after orbital reconstruction with an anatomically premolded titanium mesh can be validated with millimeter precision even using small intraoperative regions of interest (dose savings). In this way, even extensive reconstructions of the orbital floor and medial orbital wall, which otherwise require a coronal incision, can be performed exclusively via transconjunctival access, without visible scarring, through combined use of anatomically premolded implants, intraoperative navigation and intraoperative imaging (Fig. 11).

Expectations and Economic Considerations

Dose Savings Through Navigation-assisted Surgical Procedures

Multiple publications have proven that navigation-assisted procedures are capable of reducing dose for both personnel and patient [8, 13].

However, there appears to be no direct correlation between the use of a robotic system with flat detector, in particular, and additional reduction of ionizing radiation emissions. This issue needs to be re-examined in the clinical environment. Yet various options do offer hope that further dose reductions can be achieved through greater image volume and the surgeon's ability to control the system him- or herself. In particular, the memory function that allows the system to continually return to the optimal starting position probably contributes to the dose savings. Time-savings can also be expected by considerably simplifying the often tedious search for the appropriate C-arm angle.

System Integration

Integrated and networked systems can save valuable time for all involved. The ability to access the hospital information system and PACS reduces the required preparation time, and in critical situations quickly supplies all the required data. Preoperative plans can be accessed at any time.

Because the surgeon operates all the instruments personally, the OR chain of command, always a source of potential errors and often friction between professions, is no longer needed. The integrated approach dispenses with time-consuming setup, connection and readying all the necessary equipment. This also reduces the risk of damaging the often sensitive devices during frequent transport, thus keeping them available for use instead out-of-service for repairs.

Economic Aspects

Setting up a hybrid OR is costly. Some hospitals may be able to realize savings by using existing equipment.
It is important, however, to take full advantage of all the possible options. This is an essential component of the interdisciplinary approach that allows this system to be used by different departments for highly specialized interventions. This ensures that only those interventions are performed that in fact indicate the use of these types of resources. The high cost of acquisition can be justified and funds used intelligently since the room will be highly utilized and support a spectrum of indications normally reserved for major centers.

Another economic advantage is strong interest by patients in modern, innovative surgical techniques and interventions. A hybrid OR can be a strong draw in an increasingly competitive market. Yet another financial benefit of modern imaging is the option for postoperative control in an image quality that was formerly available only outside the OR. This reduces the probability of secondary revisions due to poor positioning of implants or other problems intraoperatively [4, 19]. A lower revision rate benefits patients and reduces costs, which also pays for the acquisitions over time [5, 11].

Conclusion

The hybrid OR offers the optimal platform for integrating new, forward-looking technologies. It can optimally integrate all the steps for surgical treatment: planning, transmission of planning data to the OR and the navigation solutions, the navigation system itself, and post-operative documentation, all without leaving the table. This eliminates the former time-consuming steps to transmit data between non-compatible systems. At the same time, documentation for all the steps and measures taken is completed seamlessly, without taking even more time.

Practical Application

The hybrid OR allows different medical specialties to perform highly specialized interventions, while seamlessly integrating existing technologies. Considerable time savings can be expected with technology-intensive applications, such as computer navigation.

The optimization of intraoperative imaging increases safety and quality during complex, minimally invasive interventions and offers the ability to immediately check, and if needed correct, any problems postoperatively.

High acquisition costs can be amortized using a cross-departmental utilization plan that reinforces optimal use and appropriate interventions.

The clinical as well as the economic benefits must also be evaluated from a scientific point of view to justify the establishment of this type of facility over the long term.

Conflict of interest
The author herewith certifies that no conflict of interest exists.

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Notes