1

OVERVIEW ON STRUCTURAL EVOLVING AREAS IN VASCULAR SURGERY

1.1 REORGANIZATION AND DIGITAL RENOVATION OF THE HEALTH SYSTEM: CONCRETE PERSPECTIVES IN VASCULAR SURGERY

Maurizio Taurino, Pasqualino Sirignano, Stefano Bartoli

In the last years, technology has irreversibly become entwined with all aspect of our everyday lives. From entertainments to education and to work activities, contemporary peoples spent a huge amount of their time interacting with electronic devices and benefiting from technologies development and advantages deriving form internet connection availability.

As all areas of our society, also healthcare providers and healthcare industries are facing the challenges driven by this digital renovation.

While, historically, the field of medicine, and more in general the entire healthcare section, were the sole impenetrable kingdom of few highly qualified experts, nowadays advances in technologies have promoted a digital renovation in healthcare, as both healthcare providers and patients seem to enjoy better results adopting digital solutions in addressing their needs.

Currently, these solutions are supposed to become the key element to improve patients' healthcare experience and outcomes, as demonstrated by the impressive amount of money and efforts invested in their development according to a report by the Global Market Insights Inc., estimating a digital healthcare market of 504 billion dollars worldwide by the 2025.[1]

Consequently, for every healthcare professional, including Vascular Surgeons, it is vital to be part of this ongoing digital renovation or, at least, knowing what is going on.

To be simple and direct, what is going on, this digital renovation in healthcare, is the establishing practice to use technologies and advantages related to internet connections to actively add value to patients' quality of life and healthcare system, in a manner that maximize benefits for both.

This is a crucial point: digital renovation is precisely intended to maximize benefits *via* a structured application of available technologies (or even via the development of new ones) to real-life healthcare problems. In other words, healthcare digital renovation is far from suggesting that patients surf the web to misdiagnose his/her symptoms before consulting a physician as well as from all other "*solutions*", turning people into qualified doctors.

Instead, wearable devices, internet of things (IoT), artificial intelligence (AI) applications to web based patients' portal and big-data analysis, Robotics, and dimensional (3D) printing are all promising tolls potentially providing useful information and solutions for both the patients and his/her doctor.

Furthermore, the lesson learned by the recent COVID-19 pandemic underlined the urgent need to develop infrastructures, hardware, and software, to support and to promote telemedicine and all other remote and virtual healthcare solutions.

Of course, this digital renovation has become possible only because necessary technologies were developed and spready adopted. The following are the key elements allowing the current digital renovation in healthcare.[2, 3]

ARTIFICIAL INTELLIGENCE

AI is increasingly being integrated into various aspects of medicine in general and also vascular surgery, offering opportunities to enhance patient care, improve outcomes, and streamline clinical workflows. Here are several key applications of AI in vascular surgery.[2, 3]

1. Image analysis and interpretation

AI algorithms may analyze medical imaging data such as angiograms, CT scans (Figure 1.1.1), MRI scans, and ultrasound images to assist in the detection and characterization of vascular lesions, stenosis, aneurysms, and other abnormalities, potentially facilitating diagnosis, treatment planning and intraoperative guidance. For example, AI algorithms could become able to automatically detect and quantify vascular lesions, identify anatomical landmarks and assess blood flow characteristics, helping surgeons make more informed decisions. Soon, by automating tasks like segmentation, feature extraction, and pattern recognition, AI could help vascular surgeons in evaluating complex images more efficiently and accurately.

2. Predictive modelling and risk stratification

AI techniques such as machine learning could analyze large datasets of patient characteristics, clinical outcomes, and treatment interventions to develop predictive models for various vascular conditions. These models could help stratify patients based on their risk profiles, predict treatment responses, and optimize patient selection for different interventions.

3. Surgical planning and simulation

AI-powered software tools will be able to facilitate preoperative planning by generating 3D reconstructions of vascular anatomy from imaging data, allowing surgeons to visualize patient-specific anatomy and plan optimal surgical approaches, and simulating different surgical scenarios. Surgeons could be proficient to use these virtual simulations to visualize optimal approaches, anticipate potential challenges and refine their surgical plans, before entering the operating room.

4. Intraoperative assistance and decision support

AI technologies could provide real-time guidance and assistance to surgeons during procedures by analyzing

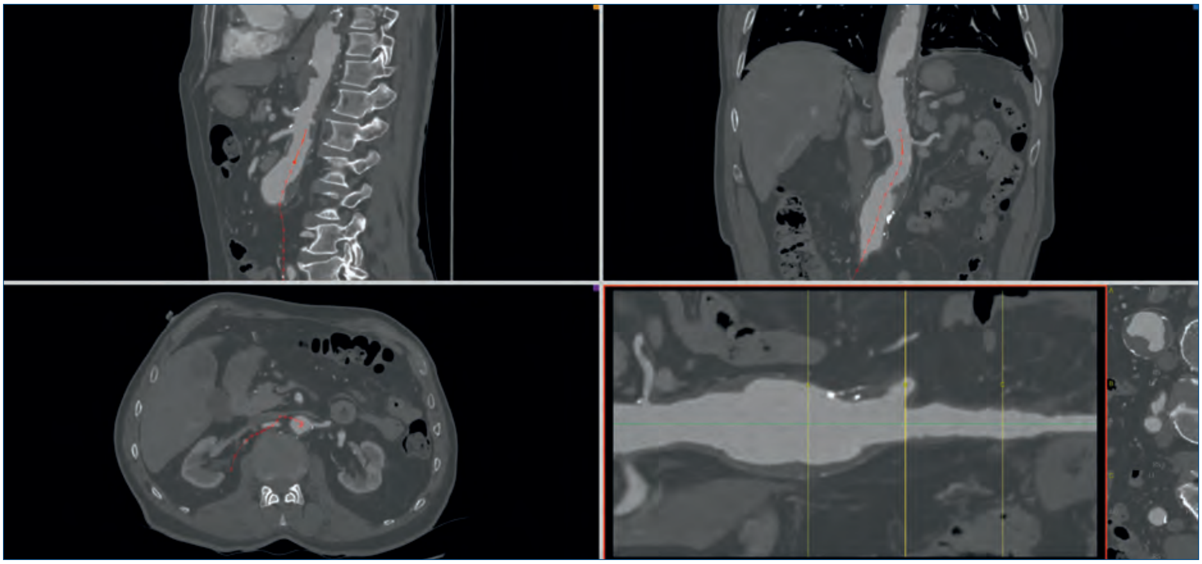

FIGURA 1.1.1 ● Multiplanar and center-lumen-line virtual reconstruction of a preoperative CTA planning an abdominal aortic aneurism intervention.

intraoperative data streams, such as physiological signals and imaging feedback, and offering decision support recommendations.

For example, AI algorithms could effectively overlay virtual images onto the surgical field, helping surgeons precisely localize vascular structures, identify critical landmarks, and navigate complex anatomical regions with greater confidence and accuracy.

5. Postoperative monitoring and follow-up

AI-enabled monitoring systems could analyze postoperative data such as vital signs, laboratory values, and patient-reported outcomes to track recovery progress, detect early signs of complications, and personalize postoperative care plans. This continuous monitoring will potentially improve patient safety and reduce the risk of adverse events and reduce hospital readmissions.

6. Clinical documentation and workflow optimization

AI-powered tools could automate routine tasks such as medical documentation, coding, and administrative tasks, allowing vascular surgeons to focus more on patient care and clinical decision-making. Natural language processing (NLP) algorithms will extract relevant information from clinical notes, streamline documentation processes, and improve the accuracy of electronic health records.

7. Clinical decision support

AI algorithms could provide decision support to surgeons by analyzing patient data, clinical guidelines, and relevant literature to offer evidence-based recommendations for diagnosis, treatment selection, and perioperative management. This will improve clinical decision-making, reducing variability in practice, and enhancing patient safety.

8. Research and innovation

AI-driven analytics could analyze large-scale clinical and genomic data to identify new insights into vascular diseases, risk factors and treatment responses. This could accelerate research efforts, facilitate the discovery of novel therapeutic targets, and drive innovation in vascular surgery. While AI holds great promise for advancing the field of vascular surgery by augmenting surgeons' capabilities, improving diagnostic accuracy, optimizing treatment strategies, and ultimately enhancing patient outcomes, it's important to address challenges such as data privacy, algorithm bias, regulatory considerations, and the need for validation and integration into clinical practice. Collaboration between clinicians, researchers, engineers and regulatory agencies is essential to ensure the safe, ethical and effective implementation of AI technologies in vascular surgery, continued research, validation and integration of AI technologies into clinical practice are essential to ensure their safety, efficacy, and widespread adoption in vascular surgery.[2, 3]

INTERNET OF THINGS

IoT devices has several possible applications in medicine and healthcare. Firstly, and more intuitively, internet connected wearable devices could collect patient's specific biometrical data in his/her daily life activities, providing the basis for a real-time highly accurate patients evaluation. Those gadgets will allow, for example, to exactly evaluate the free walking distance in patients with intermittent claudication patients, consequently driving every further therapeutic action.

ROBOTICS

For thousands of years, robots have inspired the imagination of humans, but it was only about 40 years ago that a robot was used for the first time in medicine. Since then, robot-assisted procedures have become increasingly popular in urology, general surgical specialties, and gynecology (Figure 1.1.2). Consistently, robot-assisted surgery in vascular field was introduced in 2002 to overcome the limitations of laparoscopy. However, robot-assisted vascular surgery did not yet gain widespread popularity. On the other hand, robot-assisted endovascular surgery, although still in its infancy, has become a promising alternative to existing techniques, both promoting better surgical performance and reducing occupational hazards for vascular and endovascular surgeons.

Moreover, it could be speculated that robot-assisted vascular and endovascular interventions and AI will converge to enable robot-assisted vascular surgery, where robotic systems equipped with AI capabilities assist surgeons during any kind of minimally invasive procedures: AI-powered robots will be able to manipulate surgical instruments adapting to patient-specific anatomy and offering potential benefits in terms of reduced tissue trauma, faster recovery and improved outcomes.[4]

3D PRINTING

3D printing, also known as rapid prototyping or additive manufacturing, is a novel adjunct in the medical field. This concept was first described by Hull in 1983, where accurate prototypes were created based on digital data through compound layering of thin photopolymer sheets. This technique was initially limited to automotive and aerospace engineering adaptations only due to high equipment cost. However, with the availability of cheaper commercial printers and free processing software, 3D printing has subsequently been applicable to medical science of various subspecialties, including vascular and endovascular surgery.

3D printing is now well recognized and fully incorporated as a useful adjunct in the field of vascular and endovascular surgery. The production of an accurate anatomic patient-specific replica is showing to bring significant impact in patient management in terms of anatomic understanding, procedural planning and intraoperative navigation, education, and academic research as well as patient communication.[5, 6]

Once spready available, all those technologies will benefit physicians, healthcare professionals, Hospital (and all Medical Institutions) and patients in several way.

FIGURA 1.1.2 ● An operative theater equipped with the Da Vinci Robotic Surgical Systems (Intuitive Surgical, Inc., Sunnyvale, CA – USA).

For doctors and healthcare providers digital renovation will be benefit by:

- allowing for more effective communication, and remote communication, between physicians and patients and his/her family, caregivers and patients' associations;
- allowing an easier peer to peer case revision and planning between different specialists, really useful considering how often a vascular surgeon is consulted form spoke hospitals or is involved in high complexity intervention performed from oncologic or orthopedic surgeons or, lastly, in trauma management;
- optimizing workflows by eliminating paperwork and making data more accessible;
- creating an effective and secure database for electronic medical records.
- For patient digital renovation will benefit by:
- accessing to personalized healthcare services;
- tracking his/her healthcare metrics in real-time;
- getting easier access to his/her medical data and scheduling medical appointment in a more convenient and participate way.

Of course, despite all the theoretical advantages, digital renovation must face challenges and barriers: data privacy and security concerns, natural healthcare organizations and workers' resistance to change, interoperability issue (because legacy systems and newer digital application are not always compatible) and staff shortages (physician and healthcare providers will need to update their skills to include proficiency with new digital healthcare solutions).[2,3]

The way is long, but the future is bright.

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1.2 THE REVOLUTION OF THE HYBRID ROOM: SHARED AND INTEGRATED USE OF NEW SPACES AND TECHNOLOGIES

Giovanni Tinelli, Simona Sica, Ottavia Borghese, Tommaso Donati, Antonio Luparelli, Francesca De Nigris, Yamume Tshomba

The hybrid room (HR) is an advanced procedural space dedicated to a few medical and surgical specialties, that combines features of traditional operating surgical theatres with those of image-guided interventional suites. This combination allows for highly complex surgical procedures, adding innovative radiological tasks to traditional surgical skills. The introduction of HRs in medical daily practice also has entailed a monumental shift in understanding and rationalization of workspaces, particularly within the realm of healthcare, where it is progressively gaining a pivotal role in several surgical fields, mainly including cardiac and vascular surgery, neurosurgery, urology, orthopaedics.

As regards vascular surgery, the HR is able to provide a perfect synergy between precision and innovation. By harnessing state-of-the-art imaging modalities such as fluoroscopy, computed tomography (CT), and magnetic resonance imaging (MRI), surgeons gain unparalleled insights into the complex anatomy and pathology of the vascular system. This real-time visualization enables them to navigate intricate vascular networks with confidence, ensuring precise placement of therapeutic devices and optimal patient outcomes.

The multifunctional nature of the HR extends beyond its imaging capabilities. It provides a collaborative space where interdisciplinary teams of vascular surgeons, interventional radiologists, cardiologists, and support staff can come together to strategize, execute, and monitor complex procedures. This collaborative approach fosters synergy, creativity, and innovation, driving continuous improvement in patient care and surgical outcomes.

At the heart of vascular surgery lies the quest for precision and innovation, both of which are exemplified in the HR. This dynamic environment seamlessly integrates advanced imaging technologies with surgical instrumentation, creating a synergy that enhances procedural accuracy and patient outcomes (Figure 1.2.1).

PLANNING, EQUIPMENT AND LAYOUT

The HR is used by an interdisciplinary team of surgeons, interventional cardiologists, anaesthesiologists, and others and it is good practise to involve all stakeholders deeply into planning and keeping such a facility. Planning of the HR is truly an interdisciplinary task. Clinicians and technicians of all involved disciplines should define their requirements and form a responsible planning team. The concrete planning is refined in several steps by specialized architects, vendors of operating room equipment, and imaging systems in a close feedback loop with the planning team. Virtual visualization of the room, visits of established HRs, and information exchange with experienced users help tremendously during the planning process.

Ideally, the HR is located next to interventional suites and operating rooms to keep logistics simple. However, if the operating rooms are separated from the interventional cath labs it is recommend establishing the HR next to the other operating rooms, because all equipment and personnel (e.g. heart-lung machine and perfusionists) are immediately ready and anaesthesia and intensive care is available.

A HR should be larger than a standard operating room and the basic principle for planning is the larger the better, because not only the imaging equipment ne-

FIGURE 1.2.1 ● Hybrid Room of the Hospital Fondazione Policlinico Universitario Gemelli IRCCS, Rome, Italy.

eds sufficient space. During hybrid procedures 8 to 20 people are needed in the team including anaesthesiologists, surgeons, nurses, technicians, perfusionists, experts form device companies and so forth. Expert opinions recommend for newly built operating room at least 70 m2. Additional space for a control room and a technical room is mandatory adding up with washing and prep rooms to a total of approximately 150 m2 for the whole area. Rebuilding in terms of lead shielding (2-3 mm) will be needed. Depending on the system it may be necessary to enforce the ceiling or the floor to hold the weight of the stand (approximately 650-1800 kg).[1, 2]

In addition to components of a surgical suite, the following features should be available:[3]

1. high-quality fluoroscopy (generally with flat-panel imaging) in a lead-lined room;
2. integration of other modalities, such as a biplane system, C-arm CT, integrated ultrasound, and electromagnetic navigation systems (optional);
3. a control area for radiologic technicians either inside or outside of the HR with a direct view to the surgical field;
4. a radiolucent, thin, non-metallic carbon fiber operating table that can accommodate both angiography and open operations. It must also be integrated to the imaging system to avoid collisions. Because of a lack of metal parts, some operating table functions are lost, such as isolated movement of upper or lower parts of the patient's body. Nevertheless, a floating tabletop with multidirectional tilt function is needed for accurate catheter manoeuvring;
5. adequate room size (800 square feet [74.3 m^2] to 1000 square feet or more) to accommodate the equipment required by cardiac or vascular surgeons and interventional cardiologists, as well as the anaesthesia team, nursing team, perfusionist, and radiologic technicians. Careful equipment positioning is required to allow fast conversion to conventional surgery if needed;
6. ceiling-mounted monitors placed in positions that allow all team members (surgeons, anaesthesiologists, and interventionists) to visualize the images simultaneously. Images from angiography, echocardiography, and hemodynamic monitoring need to be displayed;
7. circulating heating, ventilation, and laminar air flow to provide a smooth undisturbed air flow suitable for conventional surgical operations;
8. adequate high-output lighting for surgical interventions;
9. other inevitable requirements such as adequate number of power receptacles, gas and suction outlets for both the anaesthesia machine and the cardiopulmonary bypass (CPB) system, and hot and cold water outlets for the CPB;
10. equipment: high-definition displays and monitors, oxygen (O_2) analyser, suction, O_2 supply, defibrillator/resuscitation cart, echocardiographic equipment, sonographers, anaesthesia equipment, CPB equipment, syringe pumps, radiation protection (along with the imaging system), blood warmers and blood bank access, point-of-care laboratory monitoring for blood gases and coagulation parameters, and so on. Because of the life-threatening complications that may be encountered during the procedure, ready-made crash carts consisting of any equipment necessary in an emergency must be available;
11. a complete sterile environment.

MULTIDISCIPLINARY TEAM

One of the key advantages of the HR is its ability to facilitate interdisciplinary collaboration. In addition to its clinical utility, the HR also offers practical advantages in terms of workflow efficiency and resource utilization. By consolidating imaging and surgical capabilities into a single space, hospitals can streamline patient care pathways, reduce procedural delays, and optimize resource allocation (Figure 1.2.2).

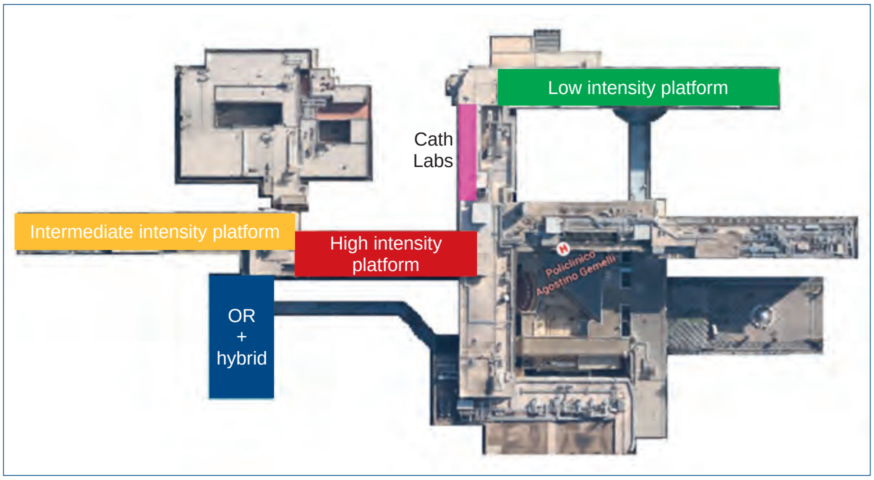

FIGURE 1.2.2 ● Cardiovascular Department of the Hospital Fondazione Policlinico Universitario Gemelli IRCCS, Rome, Italy. It is divided in three Care Units, where the patient is admitted and assisted according to the level of care needed (high, intermediate, and low). Medical and surgical patients, both pre- and postoperative, are managed by the same specialists. In this way the Cardiovascular Specialists are forced to work together in a multidisciplinary team.

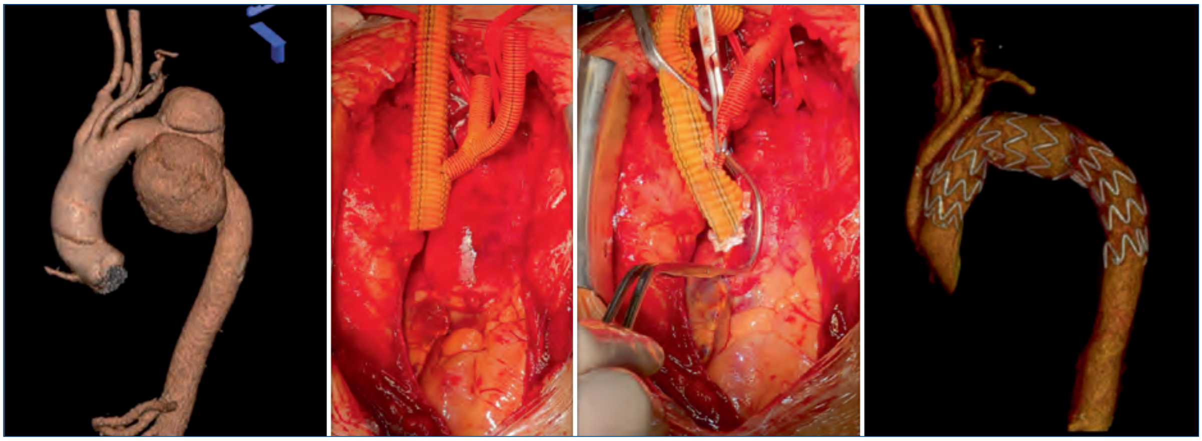

FIGURE 1.2.3 ● Personalized treatment of a giant penetrating aortic ulcer of the aortic arch with total arch debranching and TEVAR in Ishimaru Proximal Landing Zone 0 in the hybrid room setting.

This holistic approach to healthcare delivery enhances patient satisfaction and operational efficiency, ultimately benefiting both patients and healthcare providers. Furthermore, the HR's integrated communication systems enable real-time collaboration and decision-making, ensuring optimal patient care while minimizing procedural risks. Vascular surgeons, cardiac surgeons, anaesthesiologists, interventional radiologists, cardiologists, and other specialists can work together seamlessly, leveraging their respective expertise to develop personalized treatment strategies and optimize patient care.

By providing a centralized platform for multidisciplinary teams to collaborate, the HR enhances efficiency, accuracy, and safety in vascular interventions, ultimately improving patient outcomes and satisfaction.

ADVANCED CARDIOVASCULAR IMAGING

Advanced cardiovascular imaging plays a pivotal role in modern medicine, revolutionizing the diagnosis, treatment, and management of cardiovascular diseases. Through cutting-edge techniques and technologies, it provides clinicians with detailed insights into the structure and function of the aorta and its vessels enabling more accurate diagnosis, personalized treatment plans, and better patient outcomes.

One of the key benefits of advanced cardiovascular imaging is its ability to detect cardiovascular diseases at earlier stages, often before symptoms manifest. This early detection empowers healthcare providers to intervene proactively, potentially preventing the progression of diseases and reducing the risk of complications.

Moreover, advanced cardiovascular imaging techniques allow for a comprehensive assessment of cardiac and aortic function, including measures of cardiovascular anatomy, blood flow dynamics, and tissue characteristics. This holistic approach aids in the precise evaluation of cardiovascular conditions, facilitating the selection of optimal treatment strategies tailored to each patient's unique needs (Figure 1.2.3).

Furthermore, the continuous advancement of cardiovascular imaging technologies has led to improvements in imaging resolution, speed, and safety. In addition to diagnosis and treatment planning, advanced cardiovascular imaging plays a crucial role in guiding interventions. Real-time imaging, like the fusion imaging technique, cone-bone technique, CO_2 DSA, intravascular ultrasound during these procedures, in a HR setting, enhances their safety and efficacy, leading to better outcomes for patients. From the comprehensive characterization of vascular pathology to the precise sizing and deployment of endovascular devices, advanced cardiovascular imaging technologies play a pivotal role in optimizing procedural outcomes and minimizing the risk of complications.[4, 5]

Imaging fusion technique

Fusion imaging is a technique that allows three-dimensional (3D) visualization of intraoperative landmarks by projecting 3D images derived from the preoperative computed tomography (CT) angiography (CTA) scan onto the two-dimensional (2D) intraoperative fluoroscopic image (2D-3D fusion imaging). Registration can be either 2D-3D, which is performed by superimposing the 3D bone model obtained from the CTA onto the bony structures on 2D fluoroscopic images (which requires two perpendicular 2D images), or 3D-3D by superimposing the CTA 3D bone model and aortic calcifications on to a 3D bone model obtained from an on-table cone-beam CT.[4]

Image fusion of aortic 3D volume rendering on live 2D fluoroscopy provides an accurate imaging guidance during endovascular procedures (Figure 1.2.4). As the fused aortic 3D model automatically follows table and detector movements, anatomy centering does not require fluoroscopy. In our experience, before each procedure, a bone and an aortic 3D model are reconstructed from the preoperative CTA on a workstation and then fused with live fluoroscopy. The registration of this 3D preoperative model is performed using bone landmarks visible on two