The OR of the Future

The operating room of the future will include advanced technology, new OR architecture, and redefined work processes to enhance safety, improve OR throughput, and decrease costs

Walk into an operating suite today, and you are likely to see a very crowded room with a rat's nest of wires attached to bulky equipment and doctors and nurses who are bumping into each other trying to access a patient, read a monitor, or adjust an instrument. Not exactly the ideal environment for staff or patients, and not very conducive to overall work flow, efficiency, or even safety.

At the 56th Annual Meeting of the **American Society of Anesthesiologists** (ASA), held in San Francisco in October 2003, researchers from **Massachusetts General Hospital** (Boston, MA) and the **Center for Integration of Medicine and Innovative Technology** (CIMIT; Cambridge, MA) gave attendees a glimpse of the operating room (OR) of tomorrow—and the future looks a whole lot different. In their Operating Room of the Future (ORF) Project, the team is assessing perioperative processes using advanced technology, changes in OR architecture, and redefined work processes to enhance safety, improve OR throughput, and decrease costs. The anesthesiologist plays a major role in these processes, designing anesthesia care and overseeing patient safety and work flow.

The Future Is Now

In the ORF, the room itself, designed after traditional European ORs, is 100 square feet larger than most U.S. ORs and includes an induction room and a space for early recovery. Monitors and cameras are placed strategically around the room so they can be viewed by any member of the surgical team, no matter how crowded the room gets, and can be viewed remotely if so desired. There are just one or two cables attached to equipment that is compact, boom-mounted, and off the floor so it can be moved out of the way or used as needed. The OR table serves as both a transporter and OR tabletop, eliminating surface-to-surface transfers. It also has monitoring capabilities integrated in its surface to allow for continuous patient monitoring. The entire OR suite is integrated with a centralized control unit where surgeons can, with one touch, display X-ray images on a screen, access patient records, review lab results or tissue biopsies, reposition the OR table, change the music, and control room and surgical lighting. Surgeons can also transfer images to physicians outside the OR via the Internet and video conferencing.

The ORF staff is also restructured and includes a nurse that admits patients to the OR suite and provides early recovery care. Staff and patients are "tagged" with radiofrequency (RF) devices that show identifying information and can track supplies. Workflow is tracked with an indoor global positioning system that follows the footsteps of equipment, patients, nurses, and physicians in real time.

Saves Time and Money?

At the ASA, researchers presented preliminary results of an outcome study that looked at the ORF and how advanced technology and redesigning OR workspace and anesthesia workflow affects anesthesia efficiency. Data were collected prospectively on 45 patients balanced between ORF and controls undergoing general surgery, gynecology, and urology procedures. The control group included the same surgeons operating in standard ORs. Results showed mean presurgical wait time was reduced to 12.1 minutes in the ORF versus 29.9 minutes for the control group ($p<0.01$). The significant reductions in preop anesthesia time were due to parallel processing of room set up and anesthesia induction, which saved about 15 minutes per case. Researchers say the mobile OR tabletop system, with integrated monitoring, was also an important factor in facilitating this time savings. The mean emergence time of patients in the ORF group was 8.3 minutes versus 15.6 minutes for the control ORs. These time savings allowed up to four additional cases to be performed per full workday in the ORF. Currently, researchers are evaluating the overall effect of these time savings on revenue and conducting a cost/benefit analysis that will be included in their final analyses. Figure 3, p. 7, shows the floor plan and work flow of the OR of the Future at Massachusetts General.

Industrial Partners

Several medical device manufacturers are

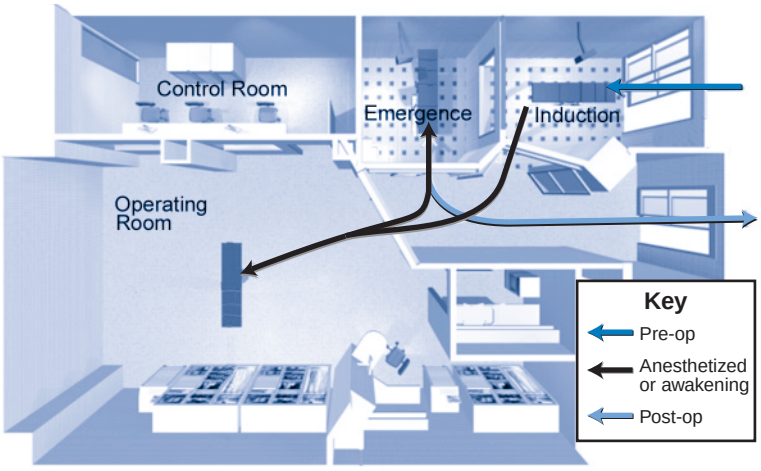
industrial partners in the ORF Project, providing key technology and consulting services (Figure 4). These include DRAEGER MEDICAL (Lubeck, Germany), MOBILE ASPECTS (Pittsburgh, PA), KARL STORZ (Culver City, CA), and GETINGE USA (Rochester, NY), as well as many others, including several prominent suppliers such as GE MEDICAL SYSTEMS (GEMS; Milwaukee, WI), J&J ETHICON ENDO-SURGERY (Cincinnati, OH), and INSTRUMENTARIUM (Helsinki, Finland; recently acquired by GEMS).

DRAEGER MEDICAL is providing its newest anesthesia machine for the ORF, the *Fabius Tiro*, which was launched at the ASA. The *Fabius Tiro* is a compact anesthesia machine designed specifically for use in ambulatory surgical centers, induction rooms, and alternate hospital sites (e.g., endoscopy suites, cysto rooms, interventional radiology suites, cardiac cath labs, etc.). It is more portable, smaller, and lighter than traditional anesthesia machines and can be boom-mounted from the ceiling or attached to the wall. According to the company, 100 *Tiro* units were sold following the ASA meeting, and the firm expected to sell a total of 250 units by the end of 2003. The *Fabius Tiro* received FDA approval in July 2003 and has a list price of $22,500.

DRAEGER is expecting FDA 510(k) clearance in the next few weeks for a pressure support ventilation option for the *Fabius GS*, another ventilator in the *Fabius* line, designed for use in the main operating room. The pressure support ventilation mode is often used for ambulatory patients that are not paralyzed or heavily anesthetized to support their natural respirations. With increasing use of laryngeal mask airways (LMA) and spontaneous breathing modes, other companies are offering pressure support ventilation options as well, including DATEX-OHMEDA (a unit of INSTRUMENTARIUM/GEMS), which launched the *PSVPro* at the ASA meeting. *PSVPro* is a pressure support ventilation mode for the company's *S/5 Avance Carestation* with the *7900 SmartVent* ventilator.

MOBILE ASPECTS is providing its patent-pending radiofrequency identification system to the ORF Program for inventory management and patient safety. For inventory management, the ORF Program is using MOBILE ASPECTS' *Secure Cabinet System*, which tags all supplies with an RF label and automatically records their use as they are removed from the cabinet. The data are sent to a computer that can be programmed to automatically reorder if it reaches a certain par level. In addition to tracking supplies, MOBILE ASPECTS is developing the *Patient Safety System*, which uses RF labeling technology to identify and track patients and doctors. This system tags patients with an RF label and tracks them as they move through the perioperative process. As patients enter the operating room, the RF reader automatically scans their identifying information, including allergies, blood type, and procedure, and displays it on the monitor for everyone in the room to see. The information is integrated with the supplies and surgeons' RF label and will alarm if the wrong blood or medication are brought into the room. MOBILE ASPECTS received an SBIR grant to develop the *Patient Safety System* and is using this experience with the ORF Program to further develop and refine the product. The

Figure 3: Floor Plan and Work Flow for the OR of the Future Project



Source: Julian Goldman, M.D., Department of Anesthesia, Massachusetts General Hospital (Boston, MA)

Figure 4: Industrial Partners with CIMIT/MGH Operating Room of the Future Project

Company	Technology Contributed to ORF
B-K MEDICAL SYSTEMS	Laparoscopic ultrasound machine
DRAEGER MEDICAL SYSTEMS	Anesthesia machines
GE MEDICAL SYSTEMS	Patient monitoring system
GETINGE USA	Patient transport/OR table system, booms & carts, surgical lights, sterilizer
HARVARD CLINICAL TECHNOLOGIES	IV pumps
INSTRUMENTARIUM	IT integration system
J&J/ETHICON ENDOSURGERY	Ultrasonic scalpel, mono- and bipolar cautery system
KARL STORZ ENDOSCOPY-AMERICA	*OR-1* integrated system
MOBILE ASPECTS	Radiofrequency identification system (RFID)
OMNICELL	"Smart" storage cabinets
PENTAX PRECISION INSTRUMENT	Video gastroscope and colonoscope, and processor
RADIANSE	Indoor global positioning system (IPS)

Sources: Center for Integration of Medicine and Innovative Technology (CIMIT) (Cambridge, MA), and MEDTECH INSIGHT

company is also developing RF technology for other applications and received another SBIR grant to develop the *Smart Anesthesia Workstation*, which will track the use of anesthesia supplies and medications.

KARL STORZ has contributed its *OR1* system to the ORF. The *OR1* system, which has been on the market since 2001, fully integrates the technology in the operating room environment and serves as the backbone of the ORF. It uses sophisticated electronic guidance systems to centralize the control of every component of the surgical suite, including overhead mounting systems, surgical lights, operating room tables, endoscopic equipment, cameras, video systems, digital documentation, data storage, and telecommunications technology. It is a modular system with open-system technology that allows any technology in the operating room to be integrated. Its routing capabilities allow surgeons to capture images and data and distribute them via a hospital Intranet or the Internet. For example, surgeons can choose to split a monitor screen and show the surgical field, a patient's vital signs, lab results, and X-rays and route it to the pathologist's office to view in real time. Company representatives say their future strategy for *OR1* includes partnering with other manufacturers that are the "best in class" to create bidirectional connectivity throughout the healthcare system. For example, to enable surgeons to access patient records through the system, KARL STORZ partnered with SIEMENS MEDICAL (Iselin, NJ) in December 2002. This partnership allows surgeons, for the first time, to capture images in the operating room and simultaneously make them part of the medical record. KARL STORZ also partnered with STERIS (Mentor, OH) and BERCHTOLD (Charleston, SC) to provide boom mounting and columns that support the various technologies.

This year, KARL STORZ will begin installing its new *OP Server* system, a boom-mounted device that incorporates numerous OR technologies into one small unit

Since 2001, KARL STORZ has installed the *OR1* in over 450 operating rooms in the U.S. Company representatives say they expect double-digit growth in this area to continue for the next five years, fueled by a recent boom in hospital renovations, retrofitting to meet seismic requirements, and new hospital construction. Price decreases are also driving the market, as prices for *OR1* have come down considerably in the past two years. This has allowed many community hospitals with limited budgets to install the system. Since *OR1* is a custom solution, prices vary considerably and can range from as little as $50,000 for a basic system to as much as $500,000, depending on what is included.

KARL STORZ's future product strategy includes designing technology that is miniaturized, modular, and remote. For example, in July 2003, the company received FDA approval for the *OP Server*, a device that incorporates numerous OR technologies into one small unit. The *OP Server* is a boom-mounted system that includes a light source, camera, insufflator, cautery, pump, and fluids system all in one compact unit that measures only 2.5-feet wide by 1-foot high. Incorporating all these technologies with traditional products would require at least a seven-foot high cart. The company is conducting product evaluation on the *OP Server* and is making modifications as needed; it hopes to begin installing *OP Server* systems in 2004.

GETINGE USA (Rochester, NY), a subsidiary of GETINGE AB, which acquired MAQUET in November 2000, is providing the operating table system that has been central to much of the time savings realized in the ORF Program. The *ALPHAMAQUET 1150 System Table* includes an operating tabletop, a transporter, and a stationary operating table column. The same tabletop is used to transport patients throughout the perioperative process, serving as an OR table and/or gurney, thus, eliminating any patient transfers. Although the *ALPHAMAQUET* table has been on the U.S. market for more than 30 years, it has not been as popular here as in Europe, due to factors such as dedicated induction rooms, patient transfer rooms, and different layouts in hospital designs. GETINGE USA is currently working in concert with the ORF Program to integrate monitoring equipment, oxygen supply, etc. to the tabletop/transporter in order to avoid any interruptions during transfer.

GETINGE is also developing table systems that will integrate with imaging systems. Outside the U.S., the company has two products available that are compatible with typical C-arms and CT scanners: the *VIWAS (Vascular*

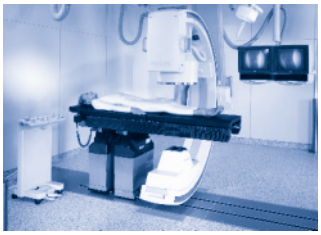
Interventional Workplace for Advanced Surgery) and *AWIGS (Advanced Workplace for Image Guided Surgery)* in two table designs. One design is made completely of carbon fiber for maximum imaging access and the other has a 3-sectional top that is similar in concept to a general surgical table. These tables move along a track system built into the floor with unique columns that support the top (columns move along both the x and y axes). Today, the *VIWAS* and *AWIGS* systems work with typical C-arm and CT scanners (see Figure 5); in the future, they will be integrated with MRI units. The company has installed about 20 *VIWAS/AWIGS* systems worldwide and anticipates U.S. market introduction in late 2004.

Global Positioning System

RADIANSE (Lawrence, MA) is a three-year-old start-up company that is providing an indoor global positioning system (IPS) to the ORF Program. Although the main application for IPS technology is to track lost equipment and prevent asset loss, the ORF Program is using an IPS to optimize the work flow of all members of the surgical team in real time, including patient flow time, wait time, procedure time, and resource utilization. The IPS consists of a transmitter and a receiver that has a radius of 30 feet. Multiple receivers can be placed throughout the hospital for maximum tracking coverage, which is analogous to a cell phone transmitting in areas where there are cells. The IPS is a completely open system that is HIPAA compliant and doesn't interfere with existing medical equipment and currently existing hospital information systems. In addition to using IPS for optimal team design and performance, researchers plan to use IPS to develop smart, real-time systems that will monitor the patient and the surgical environment so that errors are prevented before they can occur and so that key information will be available and displayed at appropriate times. To address privacy issues, the RADIANSE IPS allows user control to turn off the tracking. The company also offers a panic button feature so the device may be used for employee safety as well.

The RADIANSE IPS is approved by the Federal Communications Commission (FCC) and was released on the U.S. market in November 2003. In addition to being used by the ORF Program, the RADIANSE IPS is being beta tested at several European hospitals and the company plans to launch it internationally in early 2004. The technology costs $8 to $30 per tag, depending on its configuration and whether it includes security features, extended battery life, etc. The list price for the receiver is $350 each. Company representatives say the IPS will be installed in two U.S. hospitals after it is released on the market in the next few weeks. The firm is also in negotiations with most major manufacturers, including GEMS, WELCH ALLYN MEDICAL PRODUCTS (Skaneateles, NY), and PHILIPS MEDICAL SYSTEMS (Best, The Netherlands), to incorporate the IPS into existing technology. RADIANSE is currently engaged in a Series B funding round.

Figure 5: The GETINGE OR Table



Source: GETINGE

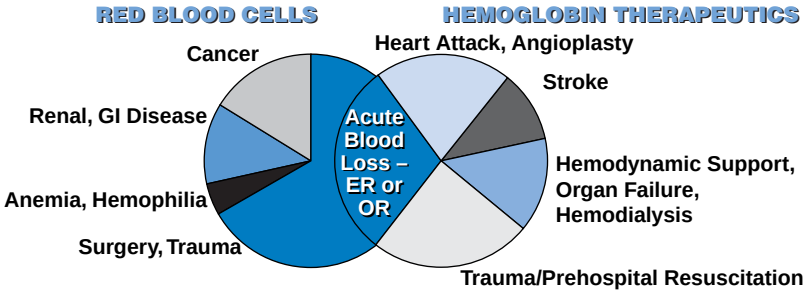
Indoor global positioning systems have the potential to improve OR work flow and resource utilization and may help prevent errors before they occur

Blood Substitutes from Page 5

incompatibility to donated blood. Figure 6 looks at the potential applications of red blood cells versus blood substitute products.

Dr. Proctor explained to the ACS audience that known HBOC safety issues, including vasoconstriction, cardiac lesions, GI discomfort, procoagulant activity, oxidative stress, pancreatitis, synergy with endotoxin, bacterial translocation across gut, and neurotoxicity, are serious issues that will need to be addressed before these products are approved and accepted into general medical practice.

Figure 6: Potential Applications of Red Blood Cells vs. Blood Substitute Products



Source: Stephen M. Cohn, MD, FACS, The Robert Zeppa Professor of Surgery, Chief, Divisions of Trauma and Surgical Critical Care, Medical Director, Ryder Trauma Center, University of Miami School of Medicine (Miami, FL), from his presentation at the October 2003 American College of Surgeons conference, entitled "Blood Substitutes: The FDA Perspective"