MEDICAL ELECTRONICS

Computer-aided surgery experiments with robotics
Fast MRI promises real-time imaging
Ultrasound rebounds
Gallstone lithotripsy questioned

A combination of technological advances in magnetic resonance imaging (MRI) is unveiling new horizons for brain surgery. No longer seen as merely a diagnostic tool, MRI, which images soft tissues by applying a strong magnetic field and radio-frequency pulses to the body, is beginning to be viewed as a powerful adjunct in the operating room, providing positioning guidance and treatment feedback.

The use of MRI for detecting phosphorus and other elements in tissue, known as magnetic resonance spectroscopy (MRS), may have found its first clinical application in diagnosing coronary artery disease. New applications for ultrasound are cropping up as well, thanks to improvements in sensor technology. Last year also brought about steady advances in biomagnetic imaging.

Neurosurgeons have always used medical images to guide them in locating tumors and aneurysms. But the greater spatial resolution of MRI (now less than a millimeter), as well as improvements in three-dimensional reconstructions of MR images, have enabled physicians to rely more heavily on the images for presurgical planning. Radiologists at the University of Chicago Hospitals are fusing MRI and positron emission tomography (PET) images to give the surgeon a more complete picture of the patient's neurological landscape.

Thus, lesions and epileptic regions that can be seen only with PET (which detects chemical and metabolic activity) can be located with respect to anatomical landmarks that show up on the MR images. The Chicago radiologists are just beginning to integrate a third imaging method, MR angiography, which detects blood flow, to map the blood vessel network on top of the PET/MRI scan.

Karen Fitzgerald Associate Editor

MRI 3-D reconstruction is proving more valuable than CT reconstruction because MRI can distinguish not just bone and tissue, as CT does, but also the different types of tissue, such as fat or lesions, and fluids, according to Ferenc A. Jolesz, associate professor of radiology at Harvard Medical School, Cambridge, Mass., and director of MRI at Brigham and Women's Hospital in Boston.

Jolesz' group has made significant improvements in MRI 3-D reconstruction by optimizing the way the 2-D images are acquired and processed in order to produce greater contrast between tissues when the images are reconstructed, according to radiologist Ron Kikinis, who is working with Jolesz. The imaging data are acquired in a double echo—a scan of the patient in which two different sets of brightness parameters are applied to better differentiate various tissues. The data then undergo a multi-stage image-processing procedure. First, they are filtered to reduce noise. Then, each pixel is classified into one of several user-defined groups—for example, gray matter, white matter, and fluids—by means of supervised multivariate analysis. (This technique was originally developed for processing remotely sensed images.)

Finally, a connectivity algorithm transforms the data into a 3-D volume. The 3-D images help the surgeon to navigate the best pathway into the brain, avoiding the motor cortex (injury to which can cause palsy or loss of visual or aural sensation), and to calculate the volume of tumors and other abnormalities.

QUALITY OF LIFE TAKES THE SPOTLIGHT

CHARLES J. ROBINSON: EXPERT OPINION

'As issues involving sustaining life are settled, the concept of quality of life is coming to the forefront of biomedical engineering.'

The increasing sophistication of medical devices invokes awe even in those of us who are practitioners in biomedical engineering. Often such sophistication so overwhelms the general public and the medical profession that it crowds out other important considerations. As issues involving sustaining life are settled, the concept of quality of life is coming to the forefront of biomedical engineering. Though that concept has existed explicitly in the rehabilitation field for years, it has been only implicit in almost all other areas of biomedical engineering. The next decade will see many devices evolving out of this concept.

Perhaps the best way to define these quality-of-life improvements is to give specific examples from diverse areas. Cardiac pacemakers have been saving lives since the 1950s and are now being installed worldwide at a rate of 125 000 implants per year. Today, many people live longer because of them. Although some might argue that simply keeping patients alive is of prime importance, extending life need not mean a continuation of a productive life, especially if the pacing device has a limited ability to respond to different situations.

An advance in quality of life occurred here a few years ago when rate-sensitive pacemakers became available. To sense body motion to determine how fast the heart should be beating, these pacemakers currently use accelerometers, but these can be fooled into responding to environmental conditions (traveling over a bumpy road) or not responding in other circumstances (such as pedaling a stationary exercise bicycle).

Further gains will be made within the next few years as a number of pacemaker companies race to implement rate-sensing schemes based on physiological principles. These schemes require the development of new implanted sensors that can reliably measure such physiological factors as oxygen saturation, blood temperature, and respiratory rate. Since these endogenous parameters are used by the body to regulate heart rate, their appropriate use as inputs to a pacemaker could represent the ultimate in pacing control strategies that optimize quality-of-life possibilities.

Sometimes seemingly incremental gains in technology can lead to major gains in quality of life. To the public, a pacemaker with a battery life of six to eight years is marginally better than a pacemaker (or an automatic implanted defibrillator) with a life of four or five years. But, to the pacemaker user, it means far less surgery and perhaps much lower health care costs.

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A Sun Sparc workstation simulates locating a tumor in the brain with a needle held in position by a stereotaxic device, a mechanical positioning system used in surgery. The two-dimensional MR images were reconstructed to form the three-dimensional volume shown, with skin and part of the brain cut away to reveal the tumor in yellow.

Brigham and Women's Hospital

Craniofacial surgeon David Altobelli at Brigham is using 3-D images along with animation to simulate surgery. For example, surgery on a patient with an oversized lower jaw has been simulated to show Altobelli the precise cuts needed to normalize the jaw. These simulations are performed on a Sun Sparc workstation 370 with the addition of a custom 3-D image-processing accelerator board made by GE. The system's increased processing speed has been critical to the developments in Jolesz' group, Kikinis said.

Computer-aided surgery

Chicago radiologist David Levin and collaborators are experimenting with an interactive stereotaxic device for transferring computer-rehearsed surgical incision contours to the patient's body before an operation. Until now, surgeons have used the 3-D images only qualitatively to prepare for surgery. Levin said a new era of computer-aided surgery is in the offing.

Radiologist S. James Zinreich of Johns Hopkins Medical Institutions, Baltimore, Md., is experimenting with a robotic arm to position surgical instruments according to coordinates derived from MR images. Researchers William Bargar and Hap Paul at the University of California–Davis have successfully implanted an artificial hip in a dog using a robot arm dubbed Robodoc to carve out the opening based on data from an image. Experts believe that robots will only be able to support surgeons, not conduct operations independently; one reason is that the positioning accuracy of the robot and the MR image may not be good enough for many procedures.

Automated surgery is an offshoot of stereotaxic surgery, in which instruments are precisely positioned by using a mechanical reference system. Stereotaxic devices are typically used today

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New techniques are becoming available to make a quantitative diagnosis of the flow of blood to the heart without invasive and sometimes life-threatening angiography. In angiography, a catheter is threaded up into a heart vessel and a dye injected. Since this diagnostic procedure has rather high morbidity and mortality rates, most cardiologists use it only as a last resort. Yet it remains the "gold standard" for diagnosing and quantifying coronary artery stenosis (constriction). Recent advances in hardware and reconstruction algorithms should make it possible for coronary blood flow to be quantitatively measured by magnetic resonance imaging techniques. Such a procedure is currently being explored at the Swiss Federal Institute of Technology in Zurich and at other locations. If it proves reliable and verifiable, the technique would greatly reduce the need for angiography.

In my field of rehabilitation engineering, we can make crude attempts in the laboratory to have "the blind see, the lame walk, the deaf hear, and the mute speak" (with apologies to Luke 4:16). Yet our efforts pale in comparison to the abilities of a neurologically intact individual. Still, one commercialized rehabilitation technology does promise its users a greatly enhanced quality of life. Cochlear implants can return some hearing to those who have suffered damage to the ear's cochlea. Essentially a transducer, the cochlea is tonotopic; that is, certain sound frequencies best excite certain areas, so that high frequencies are registered by regions near the eardrum, and the lowest frequencies, by those farther into the cochlea. The implants directly stimulate the appropriate set of nerves coming from the cochlea.

While multiple cochlear electrode arrays (such as Cochlear Corp.'s 22-channel array) have been in use for a few years, the primary stumbling block has been the development of spatial stimulus "codes" that compress speech into the best pattern for activating selected electrodes. If these codes can be better adapted to individual pathology, then many more patients might benefit from these implants.

One major hurdle remains. With arguments now occurring on the appropriate use, cost, and rationing of high-technology equipment to save or prolong life, the cost of a technology that "only" improves the quality of life can be questioned. If a technically sophisticated device that significantly enhances the quality of life of the end user is too costly, it would help only select individuals rather than all who need it. The question of cost vs. benefit of quality-of-life devices will continue to be debated by medical ethicists, governments, and insurance companies.

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for biopsies and the electrocution of tiny portions of brain tissue for conditions like epilepsy. A CT or MR image is taken with the patient locked into the stereotaxic device, and then various instruments are attached to it and directed to points in the brain as determined by coordinates on the image.

Researchers have now begun to apply real-time imaging with stereotaxic surgery to get constant feedback on the progress of the operation. Jolesz and co-workers are investigating its use in laser surgery for brain tumor removal. The stereotaxic setup would direct the laser beam through an optical fiber at the tumor to kill the cancer cells. Thanks to echo-planar diffusion imaging, a recently developed MRI acquisition technique, the physician can track the diffusion of heat and stop the therapy before it harms surrounding normal tissue. The echo-planar technique measures the diffusion coefficient of tissues and then calculates temperature changes based on it.

Echo-planar imaging, developed by a number of manufacturers and researchers, offers the promise of real-time imaging because images can be acquired in only 60 milliseconds. But because the technique involves extensive modifications to existing MRI machines, other fast techniques with acquisition times less than 1 second have been developed. Siemens AG in Munich has developed turboflash, and General Electric Co., Fairfield, Conn., has developed fast SPGR and fast spin-echo—all of which require primarily software modifications. These methods perform complete scans in only a few minutes.

Jolesz' group, with the help of GE, is investigating MRI modifications that will allow the laser surgery to take place inside the scanner. (For portions of the procedure, such as inserting the needle through which the optical fiber is threaded, the patient would be partially removed from the unit.) Kikinis estimated the entire procedure would take 1-2 hours at first, but less later on with experience.

A variation on MRI, magnetic resonance spectroscopy (MRS), surprised the medical community with evidence from a Johns Hopkins study (done in collaboration with the GE R&D Center in Schenectady, N.Y.) showing it could accurately diagnose coronary artery disease. MRS has been investigated by researchers for more than a decade, but has found no useful clinical application until now. Whereas MRI detects hydrogen atoms to provide physical images of the body, MRS, which can be added to existing high-field MRI machines by changing software and detector coils, detects phosphorus and other elements and so monitors changes in tissue chemistry. Using the technique, the researchers found that the level of phosphates in heart tissue dropped during exercise with a hand grip only when the patient had poor blood supply to the heart, usually caused by clogged arteries.

Researchers are planning to compare MRS with the most common diagnosis method, an electrocardiogram taken while the patient runs on a treadmill. MRS may be more suitable for seriously ill or older patients for whom the treadmill is too strenuous, said GE laboratory manager Kirby Vosburgh. MRS might also be used to monitor angioplasty treatment, in which plaque is cleared from blood vessels by attaching balloons, mechanical cutters, lasers, or ultrasound devices to the end of a catheter.

Ultrasound in the bloodstream

Ultrasound imaging has been around for a while, but recent advances in sensor technology and its low costs compared to CT and MRI have opened up new applications for it. Particularly attractive is its use in imaging blood flow since the traditional method, X-ray angiography, requires injecting a radio-opaque iodine dye into the blood vessels through a catheter, a process that can be painful. Angiography is used to image defective heart valves, atherosclerotic plaque, or lesions in the blood vessels. The only other alternative, the recently developed MR angiography, is also noninvasive, but is much more expensive than ultrasonic color Doppler.

When first developed a few years ago, color Doppler could be applied only in cardiology, but today new sensors can pick up the slower blood flow in tissue-encased peripheral vessels. The technique directs ultrasound waves at blood vessels through the skin and detects the return frequency, which varies with blood velocity. One benefit of looking at peripheral vessels is that they indicate the success of organ transplants.

Last year, Acuson Corp., Mountain View, Calif., introduced an ultrasound device containing small vector-array sensors that have a wider field of view and can operate at two frequencies; the low frequency penetrates deeper beneath the skin, but the high frequency gives higher resolution. To get closer to the vessels or organs of interest, manufacturers are beginning to design probes that can be inserted into body cavities or swallowed.

Even smaller sensors—so small they can be inserted into blood vessels on catheters—are in the works. These sensors could be used not only for diagnosis, but as "eyes" for the physician during angioplasty. Companies producing these sensors include Diasonics Inc., Milpitas, Calif.; Endosonics Corp., Pleasanton, Calif.; Cardiovascular Imaging Systems Inc., Sunnyvale, Calif.; and Intertherapy Inc., Costa Mesa, Calif.

Interest in biomagnetic imaging continued to grow as the Japanese Government's Ministry of International Trade and Industry (MITI) formed a $44 million consortium with nine Japanese companies to develop a system for sensing the tiny magnetic fields emanating from the brain. These fields give a reading of the currents flowing in the brain, and consequently a biomagnetometer is a noninvasive indicator of localized brain function. It has been most successfully used to locate epileptic foci so that a minimum of brain tissue is removed in epileptics who must be treated surgically. It can also identify abnormal brain regions in schizophrenics and Alzheimers patients, but researchers hope to find applications in which it can affect treatment outcome. Areas of particular promise are diagnosing heart conditions and identifying regions of hearing loss to help in the design of hearing aids and cochlear implants.

Biomagnetic Technologies, San Diego, Calif., after receiving Food and Drug Administration (FDA) approval for its $2.2 million 37-channel Magnes biomagnetometer, went into full production, delivering units to University Hospitals and National Laboratory in Tokyo. Siemens also installed a 37-channel unit called the Krenikon at the University of Nuremburg but has not yet begun large-scale production.

Lithotripsy trips up

Gallstone lithotripsy received another setback when a U.S. study of 600 patients found that it had limited success. In 1989, the FDA in Rockville, Md., declined to approve two companies' lithotripters for gallstone treatment because of insufficient evidence of efficacy. Researchers led by Leslie J. Schoenfield at Cedars-Sinai Medical Center in Los Angeles reported that the shock-wave treatment eliminated the stones in only 47 percent of the patients. Of those patients taking ursodiol, a drug that prevents stone buildup after lithotripsy, only 21 percent were free of stones after six months, vs. 9 percent who took a placebo.

Removal of the gallbladder is a more effective treatment for gallstones than lithotripsy, physicians have found, and a recently developed laparoscopic method greatly simplifies gallbladder removal. With the help of a miniature television camera to guide the way, the organ can be removed through a tube inserted in a tiny incision in the abdomen. Patients recover in a few days to a week, compared to the 1-2 months for traditional surgery.◆

HIGHLIGHTS

Success: Research showed that magnetic resonance spectroscopy can detect coronary heart disease—possibly the first clinical application of the diagnostic technique.

Shortfall: The limited effectiveness of gallstone lithotripsy was further demonstrated in a study of 600 patients.

Notable: The use of volume imaging grew as an aid to stereotaxic surgery for precise positioning of instruments during brain surgery.

Newsmaker: U.S. Congress, which passed medical device law amendments that stiffened reporting requirements for defects in and adverse effects of medical devices.