For pain and other suffering, new 'fast relief' is electronic

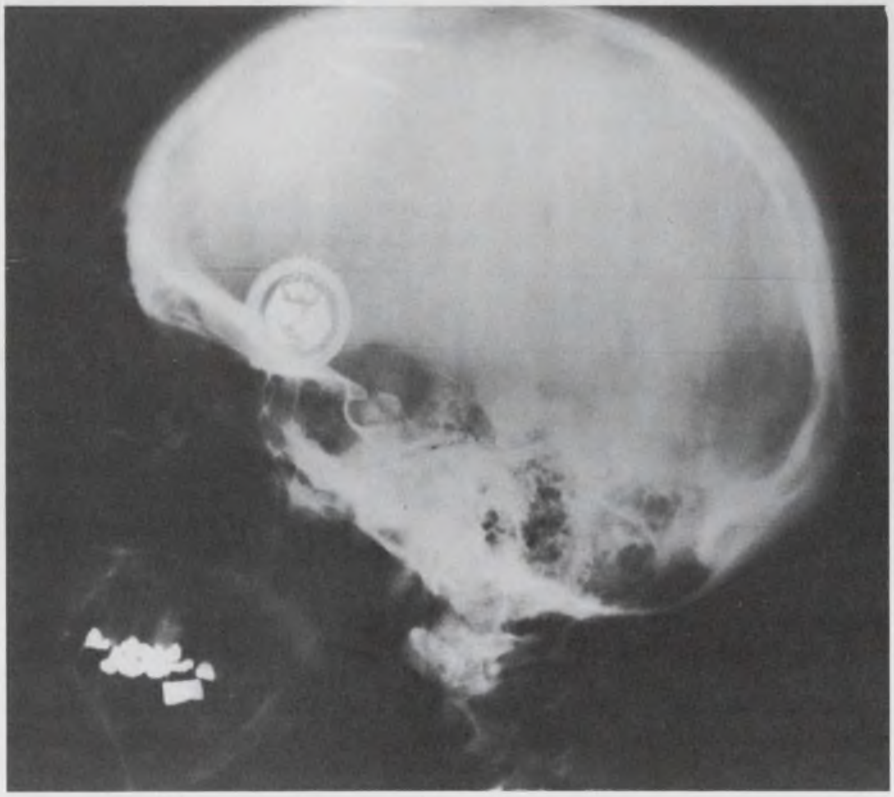
The increasing use of electronic implants in the human body has begun to offer opportunities for engineers talented in designing precise tools for surgeons and physiologists.

While much of the work in implants is still performed at medical schools and government medical centers, some companies are providing doctors with this type of equipment. Avery Laboratories, Inc., of Farmingdale, N. Y., and Medtronics, Inc., Minneapolis have developed standards for implantable electronic prosthetics that have stemmed from continued association with leading research clinicians.

In recent months surgeons have become more confident in the use of these devices, and the number of operations involving electronic implants—while not large in comparison with all operations—has increased greatly. While the types of devices are basically the same, the applications include:

- Suppressing intractable pain that cannot be eased by drugs, operations or other forms of medical therapy.
- Inducing respiration in patients suffering from hypoventilation—a decrease in the muscular action of the lungs.
- Stimulating the bladder function in paraplegic patients to eliminate colostomy bags and catheters from the stomach and urinary tract.
- Alleviating paralysis caused by strokes, spinal-cord or head injuries and possibly permitting patients to walk.
- Facilitating hearing with a tiny receiver that could last a lifetime without being removed from the patient's head.
- Pacing the heart.

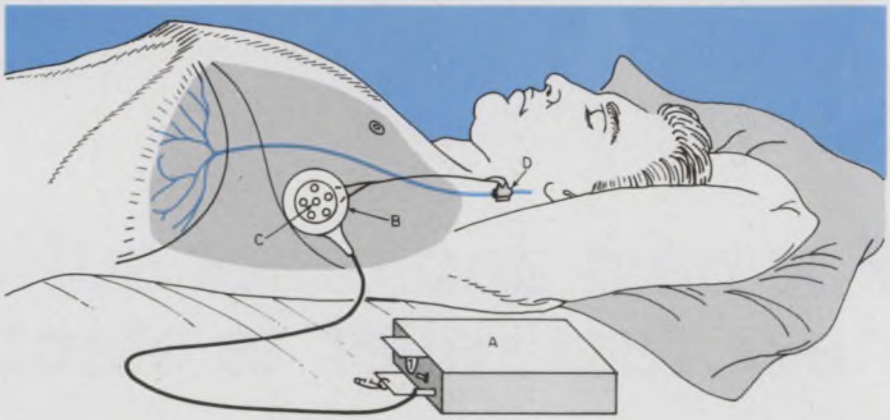
In each of these cases, batteries are not implanted in the patient. The devices operate by using an rf transformer or transmitter to couple energy through the intact body wall to the transformer's secondary coil, or to a receiver that is implanted along with the electrodes, which stimulate specific body areas. Thus the implanted part of the equipment is designed to operate for the life of the patient without being replaced. This also permits complete control of the rate, amplitude and duration of the stimulus. Also, for those patients who display signs of recovery, the stimulus can be completely turned off.



By stimulating the supraorbital branch of the trigeminal nerve, surgeons can alleviate severe facial pain. The receiver is above the eye, and the electrodes can be seen in the area of the forehead.

But the materials problems are still not solved. At the Solid-State Circuits Conference last February, Robert Huber, director of the Solid State Electronics Laboratory at General Instrument, Salt Lake City, said that a material that is absolutely inert when placed inside

Experimental neuro-stimulator consists of a transmitter with a coiled loop antenna. The antenna is placed over an implanted receiver.



Electrophrenic respiration equipment includes a battery-run transmitter (A) which transmits signals through the antenna (B) to an implanted receiver (C) connected by subcutaneous wires to implanted electrodes (D) surrounding the phrenic nerve.

the body had not been found. According to Huber, even Silastic—an epoxy-like covering—while a relatively good material for insulating implanted devices, is permeable to water and salt in the body.

The most common immediate problem with implants is the breakage of electrode wires. According to Dr. C. E. Anagnostopoulos and Dr. William W. L. Glenn, cardiovascular surgeons at the Yale University School of Medicine, "No unbreakable electrode wire has yet been developed for a bipolar system of stimulation." The factors that determine the ability of electrodes to resist breakage, they say, include the kind of metal used, the shape of the electrode, the type of waveform and the technique of placing the electrode in the body.

Electrical energy blocks pain

Although a number of theories have been formulated about the nature of pain, most pain-suppression techniques are based on empirical findings: They work.

In 1965, Dr. Ronald Melzack, professor of physiological psychology at McGill University in Montreal, and Dr. Patrick D. Wall, professor of psychology at Oxford University in England, set forth a new theory. Their "Gate Control Theory" of pain indicated that electrical energy could be used to perform a nerve-blocking function.

Roger Avery, then a consulting engineer, developed the electronics for the first neuro-stimulator for this application. The electronics consisted of a radio transmitter with a voltage and frequency control, an implantable receiver and platinum electrodes embedded in Silastic.

Dr. William H. Sweet, a neurosurgeon at Massachusetts General Hospital in Boston performed the first operation based on the "Gate Control Theory" of pain. The electronics implanted by Dr. Sweet in 1965 are still functioning, according to Karl Hallgren, marketing manager for Avery Laboratories. Hallgren says that the number of neuro-stimulators supplied by Avery in the last six years totals about 300, and that 150 such units have been sold in the last 12 months.

A critical factor in the design of the neuro-stimulator was in making the electrodes conform to the shape of the nerve. Avery accomplished this by reducing the size of the platinum electrode contacts to 1.5 $\times$ 1.75 mm. These were placed on Silastic pads 1-mm thick and 1 cm square.

Two Silastic pads, each with four platinum disks, are placed so that stimulation can be applied transversely across the nerve. This design varies, depending on the nerve to be stimulated. Each of the leadwires is made of vacuum-deposited stainless steel filaments insulated with Silastic. They connect the electrodes to an rf receiver button, which is buried in the subcutaneous tissue adjacent to the nerve. "To fit the nerves more precisely," says Dr. James P. Wepsic, neurosurgeon at Massachusetts General Hospital, "the interelectrode distance has been varied 1, 2, 3, 4, 5, 7 and 10 mm." The rf receiver button is made of high-temperature components, which allow the entire assembly to be steam-autoclaved.

Patient controls transmitter

The radio transmitter operates at a carrier frequency of 2 MHz and puts out a bi-phasic square wave. Pulse width can be varied from 50 to 300 μs and the voltage from 0 to 42 V. Pulse rate goes from 10 to 500 pulses per minute.

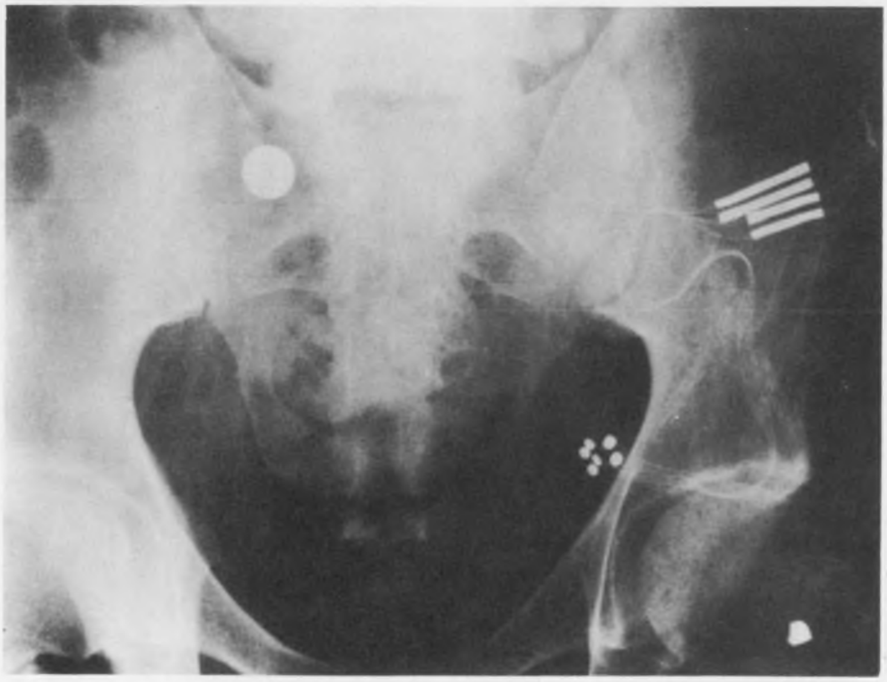
The patient can adjust both the pulse rate and the voltage. During stimulation, the transmitter's antenna is held or taped over the receiver button. This system is very similar to one being supplied by Medtronics.

While most of the operations in which neuro-stimulators are implanted are for pain in the leg or back, pain in the facial area has also been relieved with this technique.

In certain patients the breathing function can become so suppressed as to cause severe complications, such an enlarged heart. This condition is referred to as "hypoventilation" and may be caused by central-nervous-system disorders, emphysema or bulbar polio. In such cases, iron lungs or respirators are used to assist respiration.

But more than 25 years ago it was found that an electric current applied to the phrenic nerve in the neck could stimulate the motor function involved in breathing.

The technique of electrophrenic respiration was advanced in the



Stimulation of the sciatic nerve can ease pain. X-ray shows shrapnel embedded in the body. The patient, a war victim, suffered phantom limb pain. Even though his leg had been amputated, the residual nerves transmitted pain signals to the brain. This was stopped by a neuro-stimulator, whose electrodes can be seen at the left of the body's midline. The four crimps for the electrodes are shown toward the top left of the X-ray.

mid-1960s when Dr. Glenn of the Yale School of Medicine and his associates used inductive coupling to eliminate the need for wires passing through the body wall to an external power supply.

After experiments with dogs, Dr. Glenn performed the first implant operation on a human in 1965. Nine patients have undergone such operations at Yale, five of them last year.

The instrument used is similar to the neuro-stimulator, but in this case the rf signals induce electrophrenic respiration.

When the phrenic nerve is stimulated, the diaphragm descends, pulling air into the lungs. This is achieved by implanting a receiver under the skin with wires leading to electrodes at the phrenic nerve.

The carrier frequency of the transmitter is 2 MHz; pulses are 1 to 2 ms wide. Inhaling can be varied from 5 to 25 breaths per minute, but it is set typically at 17. The power is about 2 W. As with the neuro-stimulator, the antenna is usually taped to the body.

The physiological advantage of this type of respiration, compared with that performed by a respirator, is that it creates a vacuum in the lungs, which fill with air—much more in line with the actual breathing function. So far no patients with emphysema have received electrophrenic respiratory implants, but if the results continue to be positive, this technique could have far-reaching effects in aiding large numbers of such victims.

Electrical stimulation of the bladder and the bladder nerves, using rf coupling to an implanted device, has been achieved by Dr. Blaine Nashold at Duke University in Durham, N. C. While the basic technique is not new, the successful use of rf coupling with humans, after long experimental work with animals, may make this a means of eliminating catheters and colostomy bags in paraplegics.

Last year a group of doctors and engineers at Rancho Los Amigos Hospital in Downey, Calif., used a pacemaker-like device to enable partly paralyzed stroke victims to walk. The device is being built by Medtronics, with a team of Los Amigos doctors supplying medical expertise.

According to Dr. Vernon Nickel of Los Amigos Hospital, the patient wears the power pack on a belt. This is connected to a transmitter, which sends impulses to a tiny receiver, which stimulates the peroneal nerve in the leg.

A key element in the design is the triggering of the transmitter with a tiny microswitch in the heel of one of the patient's shoes. Dr. Nickel says that this switch provides the proper timing interval to enable a patient to walk.

Tiny hearing aid sought

An implantable hearing aid that stimulates the inner ear directly without a power supply was invented in 1968 by a Medtronics engineer, Rollin Denniston.

The device consists of a crystal less than half an inch long and ten-thousandths of an inch in diameter. A Teflon-coated platinum wire leads from the crystal implanted in the middle ear into the cochlea, or inner ear. From the inner ear, acoustic signals are converted to a form that can be transmitted to the brain via the auditory nerve. It is the vibration of the inner ear that performs this conversion process.

According to Dr. Jack A. Vernon, professor of otolaryngology and director of the Kresge Hearing Research Laboratory at the University of Oregon Medical School, the development of a complete hearing aid will require a tiny implantable microphone, as well as a battery pack to power the device.

At the Yale School of Medicine Wade G. Holcomb, Genichi Sato and Dr. Glenn have designed, built and tested an rf pacemaker in experimental animals. The implanted capsule contains circuitry to transmit electric current to the heart and convert received rf pulses from an external transmitter to constant-stimulus pulses. The anode electrode is attached directly to the implanted receiver.

The implanted receiver includes an electrocardiogram transmitter circuit and a secondary coil to receive the rf magnetic field from the patient's antenna. The rf voltage is converted by a rectifier circuit to dc. This supplies voltage for the electrocardiogram transmitter. The second circuit, the stimulus receiver, transmits signals to the single electrode at the heart. With both of these circuits, the cardiogram can be monitored, and if the heart fails, the organ can be paced at the proper rate. ■■