Bioengineering

Definition

Bionics (a contraction of the words biology and electronics) is a bioengineering technology that bases its designs on natural biological systems. Bionics produces both medical implants, such as cardiac pacemakers, based on the heart's own electrical conduction system, and non-medical products, such as Velcro, which was inspired by burrs clinging to a dog's coat.

Implants are devices that are surgically imbedded in body tissue. In most cases, implants are medical treatments, designed to restore or support normal biological functioning. However, not all implants are medically necessary. Breast implants are usually used for cosmetic purposes to alter appearance. And the radio frequency ID (RFID) chip, implanted under the skin, carries information that can be read by a scanner. Other implants range from heart valves to knee replacements to deep brain stimulating devices.

Here's a summary of the major types of implants currently available:

Cardiac implants
The most common heart implant is the cardiac pacemaker. About 100,000 pacemakers and over 250,000 implantable cardioverterer defibrillators (ICDs) are implanted each year in the US.[i] Both of these devices use electrical pulses to normalize the contractions of the heart muscle, and are used in patients with arrhythmias, heart failure, and other conditions. Other heart implants include stents, which open blood vessels that are clogged from atherosclerosis; and valves, which must open and close appropriately for effective pumping action. Ventricular assist devices or VADs support the action of failing ventricles, which are the major pumping chambers of the heart.[ii]

Taking things one step further is the TAH or Total Artificial Heart. These implants are currently being used as bridging devices prior to heart transplant surgery. However, it is estimated that there is a yearly potential for 100,000 TAH implants each year in the US for those with irreversible end-stage heart failure.[iii]

Joint replacements and prosthetic limbs

Surgeons in U.S. hospitals performed about 165,000 hip and 326,000 knee replacements in 2001, according to the National Center for Health Statistics. The primary cause of joint degeneration that necessitates joint replacement is osteoarthritis, a degenerative disease that attacks joint cartilage. The American Academy of Orthopedic Surgeons (AAOS) states that a hip or knee replacement lasts at least 20 years in about 80 percent of those who receive them.[iv]

Over 185,000 limb are amputations performed each year in the US and between 1.2 and 1.5 million Americans are living with limb loss. More than 65% of amputations performed on people age 50 and older are due to diabetes or peripheral vascular disease (PVD). [v] Other causes include traumatic injuries, such as those to soldiers and civilians during the war in Iraq. Elsewhere in the world, including Afghanistan and Mozambique, unexploded land mines injure thousands of people each year, which may necessitate amputation.[vi]

While most prosthetic limbs currently in use are not true implants, new types of prosthetic limbs are emerging. The first breakthrough, already in use, is the *smart leg* or C-leg, which governs itself by a microprocessor chip that reads sensors (placed in its foot and leg sections) to generate a more normal walking motion.[vii] Still in very early research stages are prosthetic limbs that have a direct link to the human brain through nervous system implants. [viii, ix]

Breast implants

While breast implants are used to reconstruct the breast after mastectomy (breast removal) surgery for cancer or traumatic injury, they are most often used in cosmetic surgeries to change breast appearance. In 2003, about 35,000 women underwent reconstruction surgery using implants after mastectomy. In that same year, more than 250,000 women underwent breast implant surgery for augmentation (to enlarge the size of the breasts). Some of the augmentation surgeries were to replace existing implants that were causing problems. Breast implants usually last about ten years. [x,xi]

Brain and other nervous system implants

Nervous system devices are being used in patients to help restore lost hearing, sight, and motor control. Implants are also being used to prevent seizures and migraines and are being explored in the treatment of depression.

Hearing

Cochlear implants bypass dysfunctional parts of the inner ear and carry sound stimulation directly to the auditory nerve. The result, while not of the quality of natural hearing, does make it possible for the patient to understand speech and so can enhance social functioning.[xii] More than 30,000 people now have cochlear implants, which can be implanted in children as young as 1 to 2 years of age.[xiii]

Sight

In use for some time, intraocular lenses are implanted after cataract removal to help restore vision.[xiv] Based on the same principal as cochlear implants, prosthetic vision implants are also being developed to restore vision. In experimental stages at present, these chips are implanted in the retina at the back of

the eye or directly into the visual cortex of the brain. [xv]

Motor control

Brain implants are being used to provide bladder control, to prevent seizures, and to control tremors from Parkinson's and other movement disorders. The treatment, called deep brain stimulation, involves a pacemaker device (implanted in the skin of the chest) that sends electrical signals to an electrode implanted in the brain. The electrical signals result in improved muscle control. (The potential to treat depression with deep brain stimulation is also being explored.)[xvi,xvii]

Military research on brain-computer interfaces

The Defense Advanced Research Projects Agency (DARPA) is researching military applications of brain-computer interfaces. One goal is to design helmets that soldiers could wear in order to “see” a robot's visual field and direct its actions from a safe distance.[xvii] Another goal is to determine whether pilots, using a brain-computer interface, could one day fly their aircraft using thought commands.[xix]

Research is underway to learn how brain chips could one day be used to control a wheelchair, and eventually, move muscles in the arms and legs.[xx] With one new implant called Braingate, an implanted sensor transmits the brain's electrical signals to a computer-interface, allowing the patient to operate the computer cursor with thought commands.[xxi]

Migraines

Clinical trials are underway to treat migraines with neurostimulators. These devices have a pacemaker unit, implanted under the skin of the back, with wires carrying pulses to nerves at the base of the skull. Another approach is the smaller rechargeable microstimulator unit that is implanted at the base of the skull; the battery charger goes under the pillow at night.[xxii]

Hardwired with Braingate

In June 2004, Matthew Nagle, a 24-year-old quadriplegic, allowed surgeons to implant a sensor into his motor cortex, the part of the brain that controls muscle movements. The sensor was connected, via electrodes and fiberoptic cable, to his computer. Leading the exploration into the brain-computer interface, Nagel now operates his computer just by thinking about it. In an amazing end-around a damaged nervous system, the sensor transmits Nagle's own brain activity, in the form of electrical impulses, to the computer, which associates signals from Nagle's brain with specific commands to the cursor. The communication link allows Nagle to check his email and play computer games using thought commands.[xxiii]

In training with his computer tech, Nagle thought of the cursor moving left or right as the computer tracked the associated neural activity for his thought commands. It took repeated trials for a consistent pattern to be established and read by the computer. At first, Nagle told a reporter, he thought about moving the computer mouse with his hand, now he just thinks about moving the cursor on the screen.

"In other words, Nagle's brain has assimilated the system. The cursor is as much a part of his self as his arms and legs were."[xxvi]

Other implants

Radio Frequency Identification (RFID) tags implanted under the skin contain information that can be "read" by electronic scanners. The information scanned is usually a code that allows computer access to that person's health information, security clearances, or financial accounts. (RFID tags are also used to track pets, wildlife, and products.)

Although not yet widely used, RFID tags or chips, as they are also called, are being marketed with the concept that they can prevent medical errors in an emergency by providing quick access to critical medical information, even if the patient is unconscious or otherwise can't communicate because of Alzheimer's or another illness. Medical records are not stored on the RFID tag, which is about the size of a grain of rice. Instead, a scanner reads a16-digit password on the tag, which gives medical personnel access to a website containing the person's emergency medical information and contacts.[xxv]

Other uses, such as security clearances, are coming into play.[xxvi] And one Barcelona nightclub uses the chip to identify VIP customers who, in turn, use it to pay their tabs.[xxvii]

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Ethical Issues

About 25 million Americans—8 to 10 percent of the population—have a surgical implant of some kind.[xxviii] They face ethical concerns when choosing and living with an implant.

Implant Recalls

Cardiac implant patients must deal with the possibility that their life-saving device may be recalled, requiring replacement surgery. The recall process for cardiac implants is not clear cut, and involves many people (but a low percentage of cardiac implant recipients).

The FDA reports that from 1990 to 2002, approximately 2.25 million pacemakers and 416,000 defibrillators were implanted in the U.S. During the same time, 8,834 pacemakers and 8,489 defibrillators were removed from patients due to confirmed device malfunction.[xxix]

How should patients be notified when their device is recalled because of the risk it may malfunction? "Patients eligible for treatment with ICDs are in a unique situation because they risk death with or without treatment," says Dr. Dianne Bartels, Associate Director of the Center for Bioethics at the University of Minnesota. "Therefore a conversation about risks would in most cases address *relative* risks: How the risk of failure of a particular device compares with the risk of death without the

intervention."[xxx]

End of Life Issues

Cardiac devices often complicate the dying process by keeping a heart beating after it would naturally cease. Discharges from cardiac devices can cause pain and anxiety and "may subject patients to a prolonged, more uncomfortable dying." Yet, ICDs are often overlooked by physicians in end of life care discussions with patients. As implantation numbers increase, physicians need to inform patients that the device may aggravate the natural dying process and ask whether they would like to request deactivation of the device to minimize discomfort as they die.[xxxi]

Ultimately, these devices need to be turned off when the patient dies, if not prior to that time.

Threats to privacy

The information on an RFID tag implanted under the skin can be read without a person's knowledge or consent.[xxxii] According to Dr. Steven Miles, professor at the Center for Bioethics and the Department of Medicine at the University of Minnesota, people may not have long-term control over who has access to the secret code implanted under the skin of the arm. Eventually, information that a patient may want to keep private, such as a family history of mental illness, may end up in the hands of health insurance companies or employers.

Enhancement versus restoring body functions

When implants are used to regain lost function in a body system, there are usually few objections to their use. But when an implant is used to enhance performance—or appearance—it becomes controversial.[xxxiii]

For example, the most common use of breast implants is in cosmetic surgeries to increase the size of the breast (breast augmentation). And use of the procedure is on the rise. From 1997 to 2002, the number of women and girls who underwent breast augmentation surgery more than doubled (from 101,176 to 249,641).[xxxiv]

However, the procedure has known risks: The implants usually last ten years but have a high incidence of serious complications within the first three years. These include "infection, hematomas and seromas, capsular contracture (a sometimes painful hardening of the breasts), loss of nipple sensation, and hypertrophic scarring."[xxxv] Women with implants are more likely not to be able to breast feed after giving birth.[xxxvi] Breast implants are *not* known to cause breast cancer. However, they may interfere with breast cancer diagnosis since they hide about one-third of the breast tissue during mammography.[xxxvii] Studies have found that breast implant recipients are at higher risk for suicide.[xxxvii]

Especially when the recipients of breast implants in cosmetic surgeries are teenagers, known to be especially sensitive about their body image, women's health advocates usually advise against the surgery.[xxxix] Others experts maintain that women have the right to give informed consent for a cosmetic procedure.

Surgical enhancement, as an attempt to alter people's self-image, has been called “psychiatry with a scalpel.” Dr. Carl Elliott, author of *Better Than Well: American Medicine Meets the American Dream* and faculty member of the University of Minnesota's Center for Bioethics, has written about this trend in medical practice in a society that is becoming increasingly absorbed in stereotypes of physical appearance: “Medical procedures that used to be seen as cosmetic are now employed to treat the psychological damage that may result from social stigma or poor self-esteem... Surgeons perform breast augmentation to prevent the stigma of having small breasts. This is not “psychiatry with a scalpel” as much as “sociology with a scalpel.” Doctors cannot fix social conditions, so they “fix” the patient instead.”[xl]

Extreme Enhancements: From humans to cyborgs?

If enhancements with implants are taken to the extreme, could we someday create cybernetic humans that are truly part machine and part human? Some computer visionaries anticipate that humans will have implantable computer chips connecting them to sensors that will increase memory and even enable new capabilities.[xli] Some experts believe that cyborgs, or humans with so many machine-made parts as to be the equivalent of cyborgs, will be apparent by mid-century.[xlii]

One such futurist is Kevin Warwick, cybernetics professor at the University of Reading, England. As a prominent researcher of the human-computer interface, Warwick conducts his research on the most available lab animal, himself. His first experiment was in 1998, when a silicon chip transponder was implanted in his forearm. This made it possible for a computer to monitor his presence and for Warwick to operate doors, lights, heaters and other computers “without lifting a finger.”[xliii]

Professor Warwick has said, "I was born human. But this was an accident of fate—a condition merely of time and place."[xliv] “The potential for humans, if we stick to our present physical form, is pretty limited. The opportunity for me to become a cyborg is extremely exciting. I can't wait to get on with it.”[xlv]

What Does it Mean to be Human?

"For bionic humans, ethical issues arise from the use of neural connections and brain-machine interfaces, centered around the question of what it means to be human. Certainly, a person who has a natural limb replaced with an artificial one has not become less human or lost a significant degree of 'personhood.' But suppose a majority of organs in an injured person is replaced by artificial components; or, suppose the artificial additions change mental capacity, memory, or personality. Is such a heavily artificial person somehow less than human? Would the established legal, medical, and ethical meanings of personhood, identity, and so on, have to be altered?"

—Sidney Perkowitz in: Digital People in Manufacturing: Making Them and Using Them

Our Sense of “Self”

Because they involve the brain and senses and so could potentially affect both self-concept and the way we perceive and interact in the world, brain and nervous system implants have become an evolving

controversy.

Some cochlear implant receivers say that they feel isolated from both the hearing and the deaf communities, because the imperfect artificial hearing that the implant provides does not allow them to feel as if they are communicating well with either group. Deaf World is a group that opposes the use of cochlear implant surgery in children, saying it could lead to a decline in the population of this minority culture.[xlvi]

At present, brain implants in humans are being used to normalize brain function so that patients regain motor control and avoid seizures. However, experiments in animals are altering the animals' perceptions of reality. Implanted brain chips are creating *virtual* perceptions, to which the animals respond as if they were real. Rats who felt their whiskers brush against a non-existent obstacle turned away as if it were real. According to Jeff Kahn, Director of the Center for Bioethics at the University of Minnesota, virtual perceptions could one day be part of human brain bionics as well. “The question is how we decide to use brain-stimulating implants. Implanted brain stimulators already are used for Parkinson's disease, but what about to alter personality disorders? What about eventually trying to improve perception and intelligence?”[xlvii]

Ray Kurzweil, innovator of both print-to-speech and text-to-speech technologies and author of “The Age of Spiritual Machines,” is confident that we will be using brain bionics to alter our perceptions:

> "In the 2020s, neural implants will not be just for disabled people. Most of us will have neural implants to improve our sensory experiences, perception, memory, and logical thinking. These implants will also plug us in directly to the World Wide Web. This technology will enable us to have virtual reality experiences with other people — or simulated people — without requiring any equipment not already in our heads. And virtual reality will not be the crude experience that people are used to today. Virtual reality will be as realistic, detailed, and subtle as real reality. So instead of just phoning a friend, you can meet in a virtual French cafe in Paris, or stroll down a virtual Champs D'Elyse, and it will seem very real. People will be able to have any type of experience with anyone — business, social, romantic, sexual — regardless of physical proximity."[xlviii]

Resource Allocation: The cost of implants

Because implants can extend the life span of recipients, widespread use will probably inflate the cost of Medicare.[xlix] A research team of economists and physicians from the RAND Corporation, Stanford University, and the Veterans Affairs Greater Los Angeles Healthcare System found that: “Medical innovations will result in better health and longer life, but they will likely increase, not decrease, Medicare spending.”[l] The report examined how Medicare coverage decisions are influencing the availability and cost to taxpayers of providing technology to recipients:

> “For example, intraventricular cardioverter defibrillators (ICDs) are very effective for patients with life-threatening arrhythmias. A recent coverage decision expands

prophylactic ICD use to patients at high risk of sudden death from ischemic cardiomyopathy. But if use is expanded to patients with other heart problems, then costs could rise very quickly. The research team simulated the effects of expanding ICD use to half of elderly patients with new cases of heart failure or heart attack. This would result in approximately 374,000 procedures annually in 2015 and 550,000 in 2030, and total treatment costs of $14 billion and $27 billion, respectively. The cost per additional year of life would be about $132,000."[li]

Improvements in medical technology driving healthcare costs upward is a global trend that shows no sign of slowing. According to Duke University physicians Daniel B. Mark and Mark A. Hlatky, "The globalization of medical development through large international mega-trials and the spread of information via the Internet suggest that technological innovation will continue to increase patient expectations and medical costs across the world. The public wants improved medical technology, yet it also wants health care to be affordable and accessible to everyone, regardless of the patient's ability to pay." [lii]

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Links

To find out more about cardiac devices and the heart conditions they are used to treat, visit the Medical Devices page from Heart Health Online, available from the FDA at http://www.fda.gov/hearthealth/treatments/medicaldevices/medicaldevices.html

For an overview of joint replacements, read " Joint Replacement: An Inside Look," by Linda Bren in the March-April 2004 issue of *FDA Consumer Magazine,* available online at http://www.fda.gov/fdac/features/2004/204_joints.html

The Amputee Coalition of America, an advocacy organization for amputees, is online at http://www.amputee-coalition.org/advocacy/appll-executive-summary.pdf

The National Research Center for Women and Families website contains an issue brief on breast implants, " What You Need to Know About Breast Implants," by Diana Zuckerman, PhD, Elizabeth Nagelin-Anderson, MA, and Elizabeth Santoro, RN, MPH *Issue Brief* - May 2005 http://www.center4research.org/implantfacts.html

For more information on breast implants, see the *FDA Breast Implant Consumer Handbook 2004* (http://www.fda.gov/cdrh/breastimplants/indexbip.html) and the FDA breast implant information mainpage (http://www.fda.gov/cdrh/breastimplants).

Information on cochlear implants can be found in “Hearing Loss” from MayoClinic.com online at http://www.mayoclinic.com/health/hearing-loss/DS00172/DSECTION=7&.)

To learn more about how deep brain stimulation works, see the National Public Radio story, “Brain Implant Offers Hope for Severely Depressed, online at http://www.npr.org/templates/story/story.php?storyId=4627438

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