

The ethical aspects of ICT implants in the human body

Proceedings of the Roundtable Debate

Amsterdam, 21 December 2004

Secretariat of the EGE

European Group on Ethics in Science and New Technologies to the European Commission

- December 2004 -

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Introduction

The European Group on Ethics (EGE) is an independent, pluralist and multidisciplinary body, which advises the European Commission on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies.

The Group is composed of twelve independent high level experts appointed by the Commission for their individual expertise and personal qualities.

During its first mandate the EGE (1998-2000) provided Opinions on subjects as diverse as human tissue banking, human embryo research, personal health data in the information society, doping in sport and human stem cell research.

In April 2001 the Commission appointed the current twelve Members for the second mandate period (2001-2004). Under this second mandate, the Group has published Opinions on the ethical aspects of patenting inventions involving human stem cells (N° 16, 7 May 2002), clinical research in developing countries (N° 17, 4 February 2003), genetic testing in the workplace (N° 18, 28 July 2003), and on umbilical cord blood banking (N° 19, 16 March 2004).

The Group is currently finalising its 20th Opinion on “***the Ethical Aspects of Information and Communication Technology (ICT) Implants in the Human Body***”.

In preparing its opinions, the EGE engages in a broad consultation, involving individual experts, representatives of European institutions and other international institutions as well as representatives of civil society. The roundtable organised by the European Group on Ethics was held on 21 December 2004, in order to promote a transparent dialogue between parties representing many different interests.

The following report is a summary of the presentations and discussions which took place in Amsterdam.

The Opinion of the Group will be published in the first quarter of 2005.

Dr Michael D. ROGERS
Head of the EGE Secretariat

ROUNDTABLE
Ethical aspects of ICT implants in the human body

Tuesday 21 December 2004, Amsterdam

Organised by the European Group on Ethics in Science and New Technologies

PROGRAMME

- | | |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 12H30– 13H30 | Lunch at the Royal Netherlands Academy of Arts and Sciences (KNAW), Kloveniersburewal 29, Amsterdam |
| 13H30 | Welcome address by Professor WJM Levels, President of the Royal Netherlands Academy of Arts and Sciences (KNAW) |
| 13H40 | Introduction to the EGE Roundtable by Professor Göran Hermerén, Chairman of the EGE |
| 13H50 | Presentation by Professor Jacques Brotchi, Head of the neuro-surgery department at the Erasmus University Hospital, Brussels, Belgium
<i>“Brain implants – scientific overview and ethical aspects”</i> |
| 14H10 | Presentation by Professor James H. Moor, Professor of Philosophy, Dartmouth College, USA
<i>“Becoming a Cyborg : Some ethical and legal implications of ICT implants”</i> |
| 14H30 | Presentation by Mr Peter Hoogendoorn, President of the Dutch Parkinson Society, The Netherlands
<i>“ICT Brain implants – A Patient’s Perspective”</i> |
| 14H50 | Presentation by Dr. Fabienne Nsanze, M.D., Brussels, Belgium
<i>“ICT implants in the human body – A review”</i> |
| 15H10 | Coffee break |
| 15H30 | Discussion with contributions from the participants |
| 16H40 | Closing comments from EGE members |
| 17H00 | End of Roundtable |

Presentations

Jacques BROTCHI

Professor Jacques Brotchi

Erasmus University Hospital, Brussels, Belgium

Biography

Born in Liege (Belgium), in 1942, Jacques Brotchi graduated in Medicine (M.D.) from the State University of Liege in 1967. He completed his training in Neurosurgery under Professor Joel Bonnal at the Neurosurgical Clinic of the University of Liege.

Since 1963, his high interest in Neurological Sciences led him to work as student and thereafter as researcher at the Laboratory of Neuroanatomy of the University of Liege where he spent 19 years with Professor Michel Alexandre Gerebtzoff, deeply involved in histoenzymology of the peripheral and central nervous system. He was awarded a Ph.D. in histochemistry of focal epilepsies. Parallel to his laboratory research, he was very busy with neurosurgical practice and published, with J. Bonnal, in all fields of Neurosurgery with special emphasis on sphenoid meningiomas and on sinus repair in parasagittal meningiomas.

In 1982, he moved from Liege to Brussels where he created the Department of Neurosurgery at Erasmus University Hospital. He is now Head of the Department (since 1982), Professor and Chairman at the Free University of Brussels (ULB) (since 1984). He is also Director of the Laboratory of Experimental Neurosurgery at the ULB.

He has trained numerous neurosurgeons among which several became Head of Department or Professor of Neurosurgery in different Belgian Universities. He has published more than 250 papers in international journals and 30 book chapters, with special emphasis on meningiomas, intraspinal cord tumours and surgical approaches of pineal lesions. He has stimulated much work in his department and emphasized the role and the use of PET-Scan combined with Neurosurgery (PET guided stereotactic biopsies, PET guided neuronavigation, and PET guided Gamma Knife treatment) as well as interventional MRI since 2001.

Member of the editorial board of several neurosurgical journals, he has been guest of honour at numerous national and international congresses and is deeply involved in the educational programme of the World Federation of Neurosurgical Societies (WFNS) (since 1991). Chairman of the WFNS Education Committee from 1997 to 2001, he has organised many courses worldwide, particularly in developing countries.

At the present time, he is President-elect of the WFNS, Coordinator of WFNS Committee Activities and Vice-Chairman of the World Health Organization Working Group in Neurosurgery.

He is Corresponding, Titular and Honorary Member of various national Neurosurgical societies. He is honoured to be President of the Belgian Neurosurgical Society, French Speaking Society of Neurosurgery, Chairman of the Brain Tumour Group of the European Organization for Research and Treatment of Cancer (EORTC).

In 1998, his department was distinguished by WHO and nominated "First Worldwide WHO Collaborating Centre for Research and Training in Neurosurgery".

In 2000, he received one of the most prestigious Belgian medical prizes: "Scientific Prize Joseph Maisin-Clinical Biomedical Sciences" within the scientific quinquennial prizes of the National Research Foundation, period 1996-2000.

Member of the Royal Academy of Medicine of Belgium, of the French Academy of Surgery and of the American Academy of Neurological Surgeons, he was awarded Commandeur de l'Ordre de Leopold of Belgium, Chevalier de la Légion d'Honneur of France, Chevalier of Danneborg Order of Denmark and Grand Commandeur of the Civil Order of Spain.

In 1988, King Baudouin of Belgium ennobled him for his contributions to Neurosurgery and Belgium.

In July 2004, he was made a Belgium Senator.

Dr. Brotchi and his wife Rachel have one daughter, Nathalie and two grandchildren, Nina and Dylan.

Brain implants – scientific overview and ethical aspects

Jacques BROTCHE

SUMMARY

Neurosurgeons are familiar with brain and peripheral implants at the level of the spinal cord and the nervous system.

However, nerve trunk stimulation and spinal cord stimulation are not sources of big ethical debates. So, my presentation will focus on brain stimulation either through cortical or deep brain electrodes. Cortical electrodes are used for epilepsy recording in the preoperative planning. Cortical stimulation is routinely used for the localization of motor strip during neurosurgery in eloquent areas or as a treatment for chronic pain relief with implanted electrodes at the surface of the brain.

Nevertheless, the main brain implants we should discuss today are deep brain stimulation for Parkinson's disease and other indications such as Obsessive-Compulsive Disorder (OCD) and perhaps the problems of obesity as well as of sexual disorders.

Those aspects raise considerable ethical debates.

PRESENTATION

Neurosurgeons are familiar with brain and peripheral implants at the level of the spinal cord and the nervous system.

Nerve trunk stimulation is being studied for paraplegic patients (SUAW project: "stand-up and walk") with some promising results. Vagus nerve stimulation (VNS) for intractable epilepsy is commonly used. VNS is also starting for treatment-resistant depressions. Spinal cord stimulation is in daily use for peripheral pain relief. Some experimental studies have been conducted to take advantage of the sympathetic effect of spinal cord stimulation in lower limb arteriopathies. However, those implants do not raise big ethical controversies.

Brain stimulation may be made through cortical stimulation (at the surface of the brain) or through deep brain stimulation with implanted electrodes. Electrodes at the surface of the brain are used for recording electrical activity in refractory epilepsy with the aim of localising the epileptic focus that could be treated by neurosurgery. The implants are also used for brain stimulation in the treatment of severe chronic pain and for the localization of the motor strip during neurosurgical procedures in eloquent areas of the brain. Those activities do not give rise to much ethical debate.

However, when we enter the field of deep brain stimulation we open a delicate window, certainly not in the case of Parkinson's disease, but definitively for other indications. For Parkinson's disease, it is evident that, at the present time, deep brain electrodes into the subthalamic nucleus with selective stimulation offers the best choice for those patients who have no relief from medical treatment. A few years ago, we had great hope in the grafting of foetal cells, which was eventually stopped because of limited long-term results. Nevertheless, the expectation of obtaining better results with other cell (stem cells for example) in the future remains a great hope since with deep brain stimulation, we treat the symptoms but not the illness itself that might be repaired by cell transplantation.

Incidentally, when implanting these electrodes in the deep thalamus, some colleagues have observed, by chance, a positive effect on obesity. At the present time, no results have been published but this could be a very important scientific and ethical topic.

What is on the way at the present time is long-term electrical capsular stimulation in patients with obsessive-compulsive disorders (OCD). Psychoneurosurgery has been performed in the past for several psychiatric disorders such as schizophrenia, depression, anxiety and OCD. The procedure was pre frontal leucotomy. The often unacceptable side effects of this treatment and the advent of psychotropic drugs, led to waning enthusiasm for psychosurgery. By the way, ethics has become more and more important in our daily life and leucotomy is no longer acceptable. Unfortunately, the prognosis of treatment-resistant affective disorders and OCD are quite poor, so these patients and their families are burdened with extreme emotional and psychic costs, as well as marked suicide risks. Therefore recently there has been a renaissance of interest in surgical approaches to psychiatric disease with new targets like the cingulum, limbic lobe or the anterior limb of the internal capsule and techniques (stereotactic capsulotomy, Gamma Knife capsulotomy or long-term electrical capsular stimulation). These procedures require very close ethical control.

One should also take advantage of modern neuro-imaging in the definition of the pathoanatomic basis of mental disorders. The interest in deep brain stimulation is the reversible possibility which is very important in psychomodulation. New, minimally invasive, or non invasive procedures based on functional imaging and an improved knowledge of psychiatric diseases may use neuroaugmentative or transplantation methods. These new methods may change the attitude of governments, psychiatrists, third-party players, and society which still equate psychoneurosurgery with the destructive procedures of the past. Randomized blind prospective studies across European centres using standardized assessment tools should be encouraged. Furthermore, one should also focus in the future on studies which could protect society against criminal paedophilia and sexual disorders of people released from jails. That cannot be made without strong ethical guidelines.

The powerpoint slides that accompanied this presentation are on the following pages.

BRAIN IMPLANTS

11

SCIENTIFIC OVERVIEW AND ETHICAL ASPECTS

Jacques Brotchi, MD, PhD

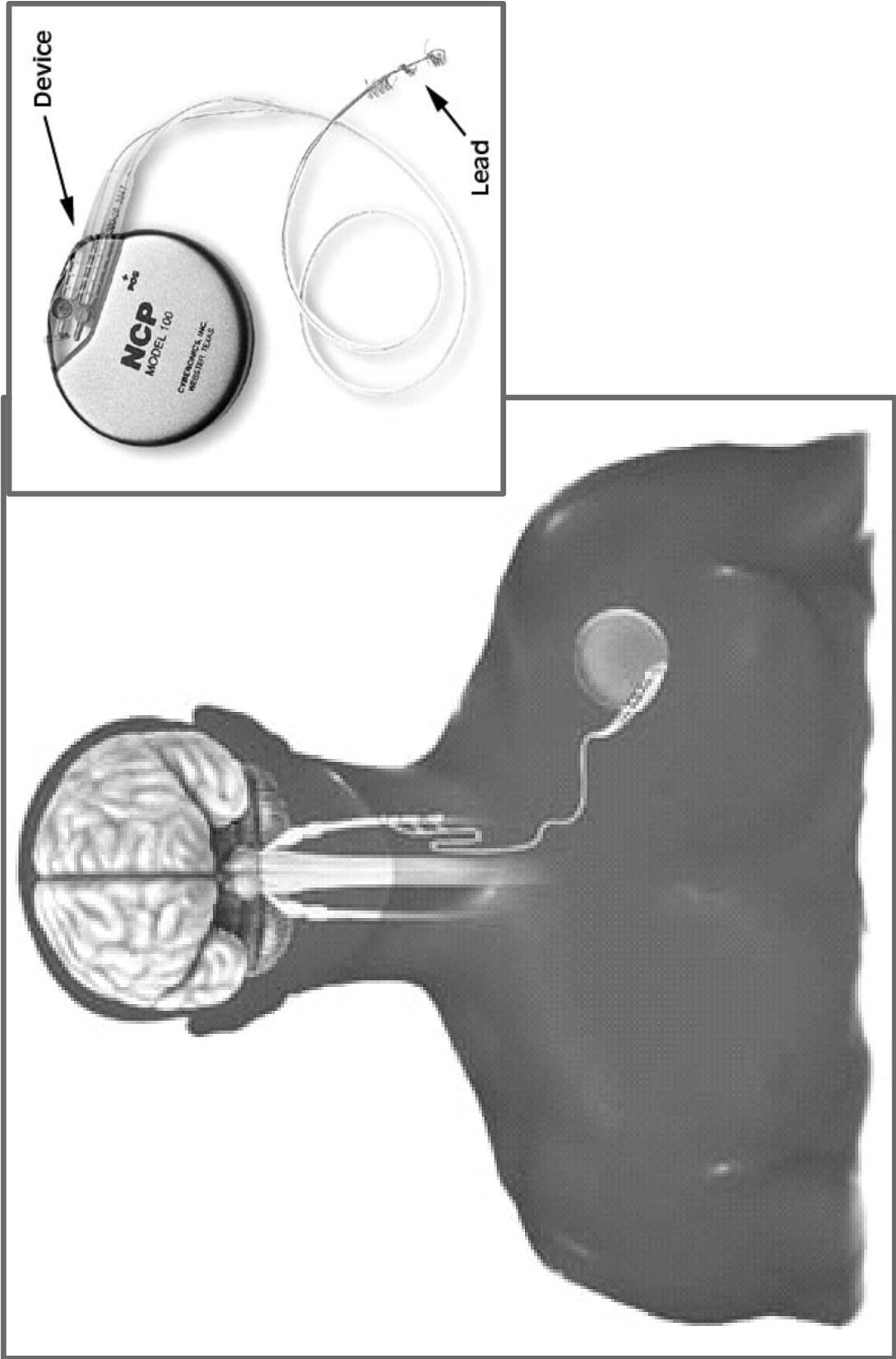
Department of Neurosurgery

Erasmus University Hospital - ULB, Brussels, Belgium

EGE ROUNDTABLE, Amsterdam, 21 December 2004

NEUROSURGICAL IMPLANTS

- Nerve trunk stimulation in paraplegia
- Vagus nerve stimulation for
 - Intractable epilepsy
 - Treatment resistant depressions
- Spinal cord stimulation for
 - Pain relief
 - Arteriopathic disease of lower limbs
- Brain implants

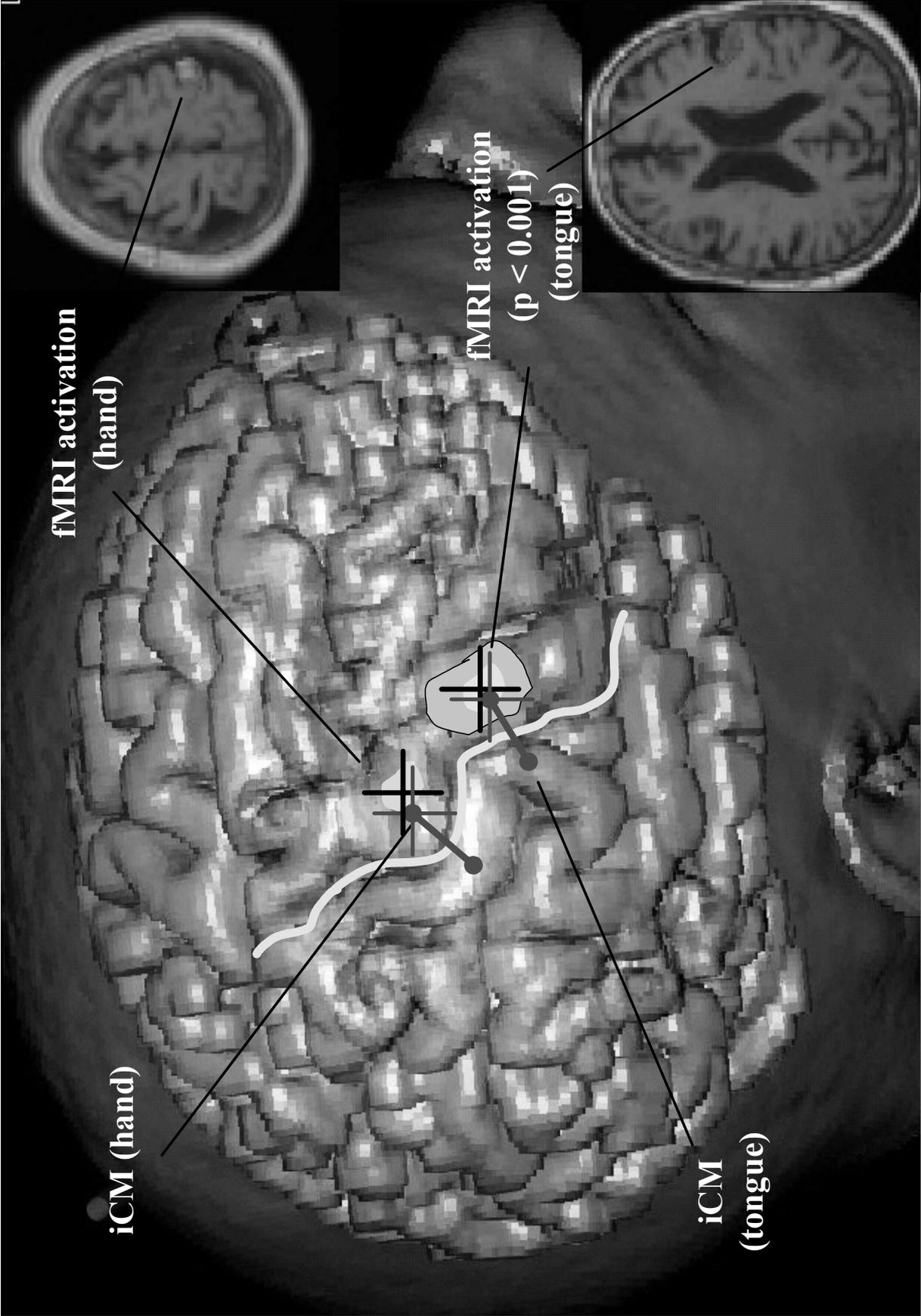


BRAIN IMPLANTS

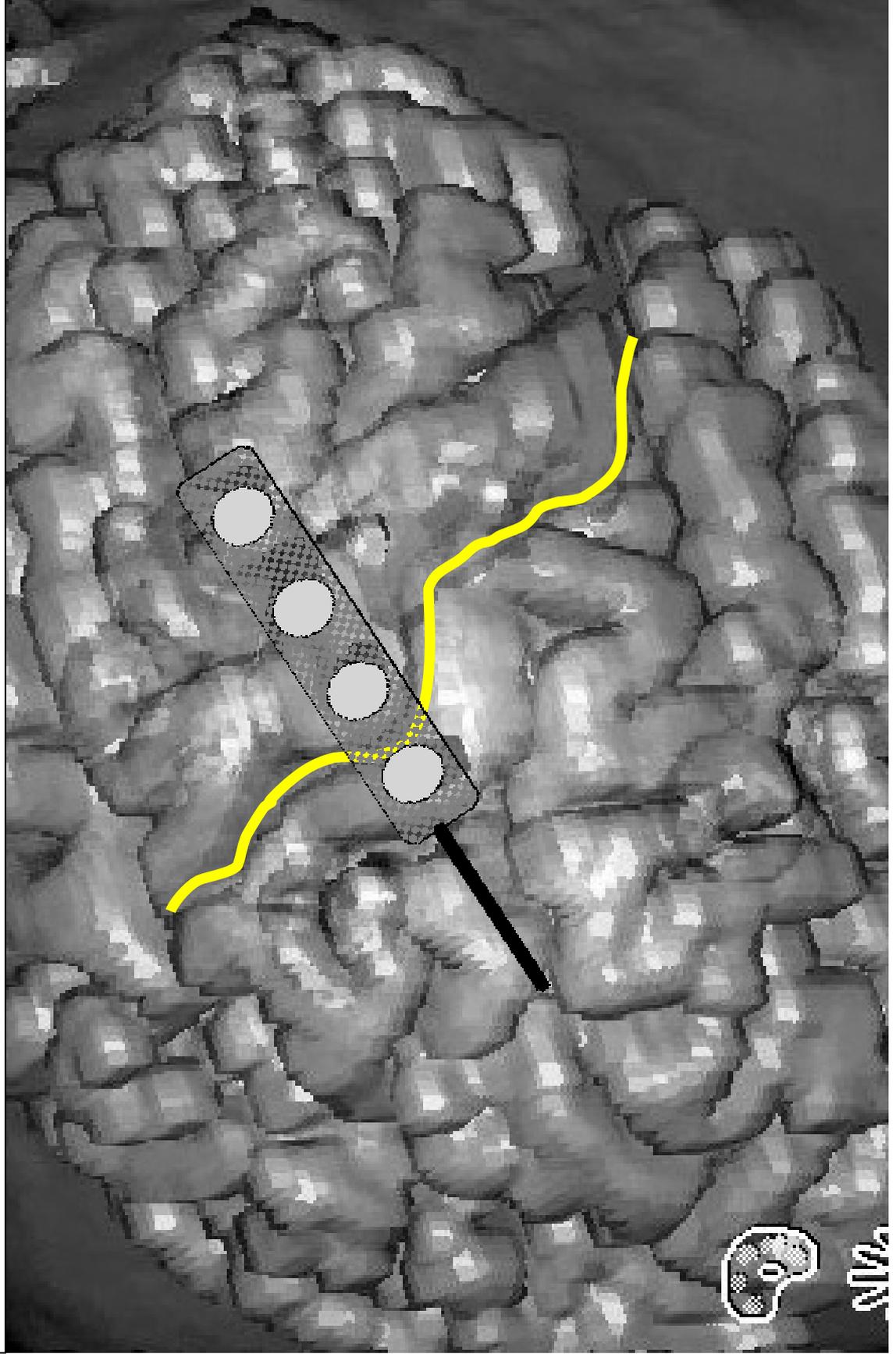
- **Surface electrodes**
 - Pain
 - Epilepsy
 - Neurosurgery in eloquent areas
- **Deep electrodes in the brain**
 - Parkinson's
 - Obsessive-Compulsive Disorder

PAIN

- Posterior ventral nucleus of the thalamus
- Chronic stimulation of the motor cortex



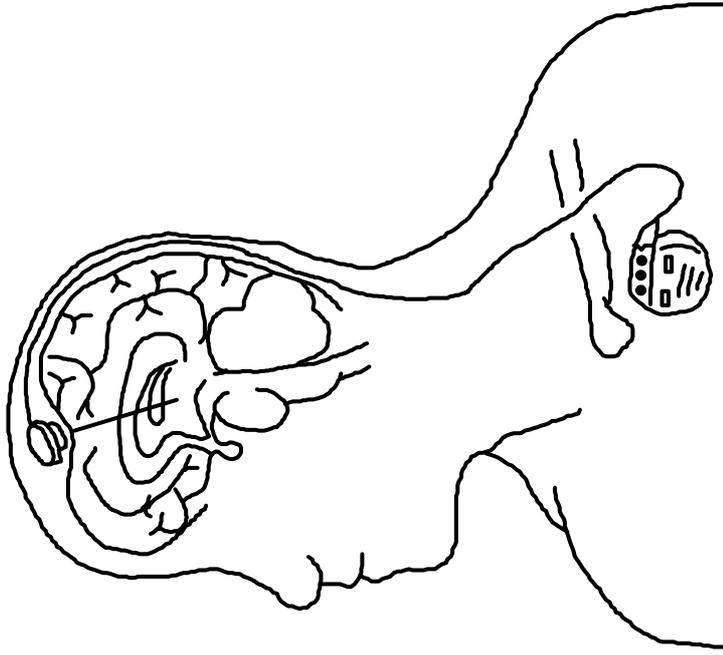
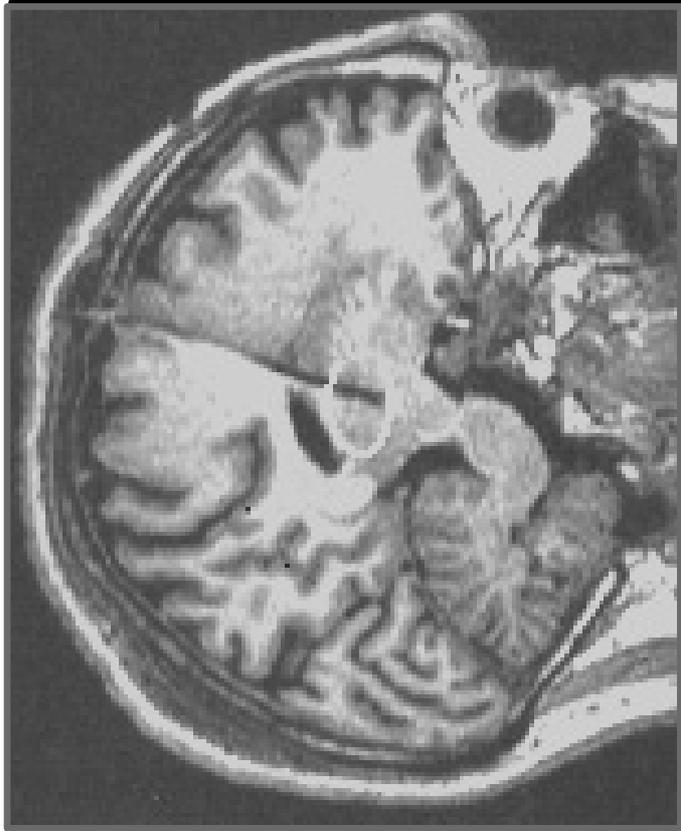
Chronic Epidural Stimulation of Motor Cortex related to painful somatic segment to alleviate pain



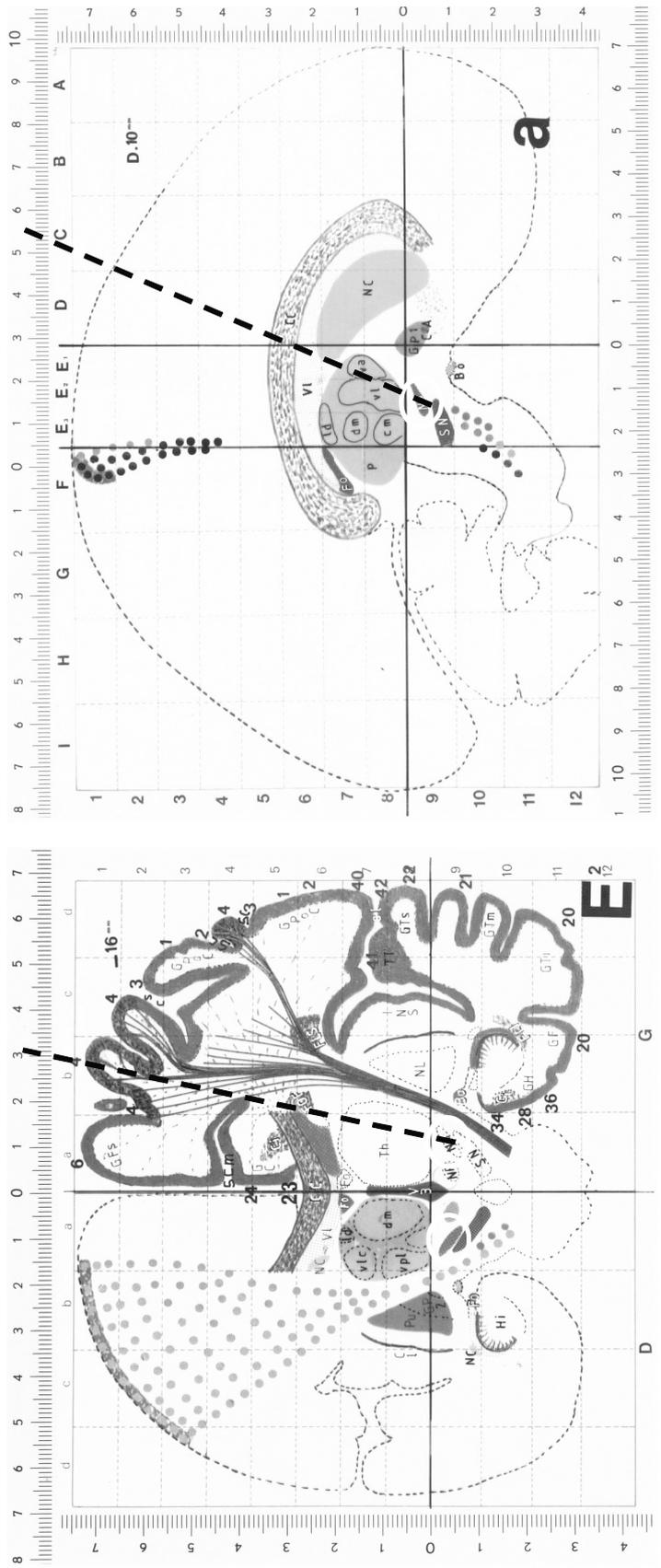
Parkinson's Disease

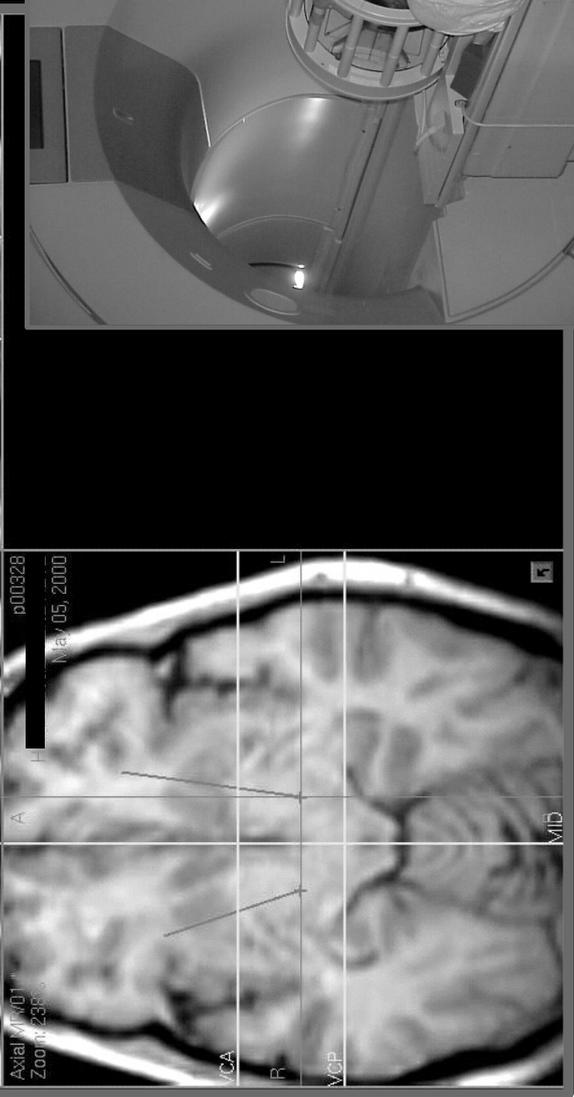
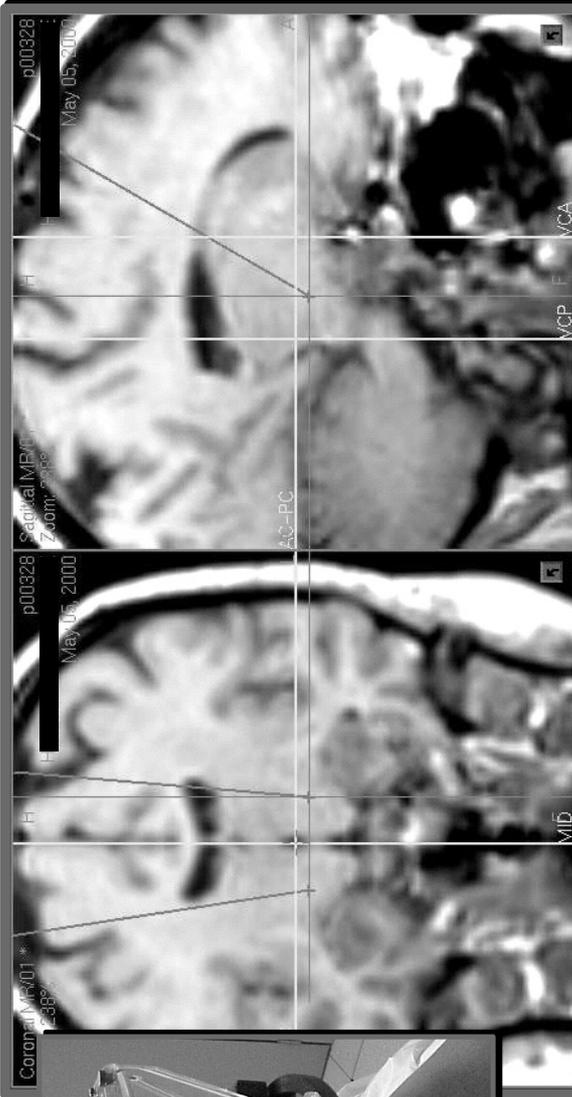
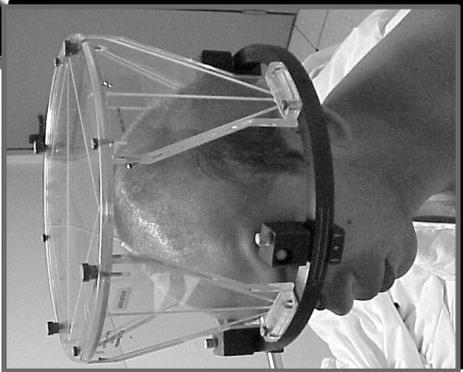
- Deep brain stimulation
 - Ventroposterolateral pallidum
 - Subthalamic nucleus
- Cell implants

Parkinson's disease

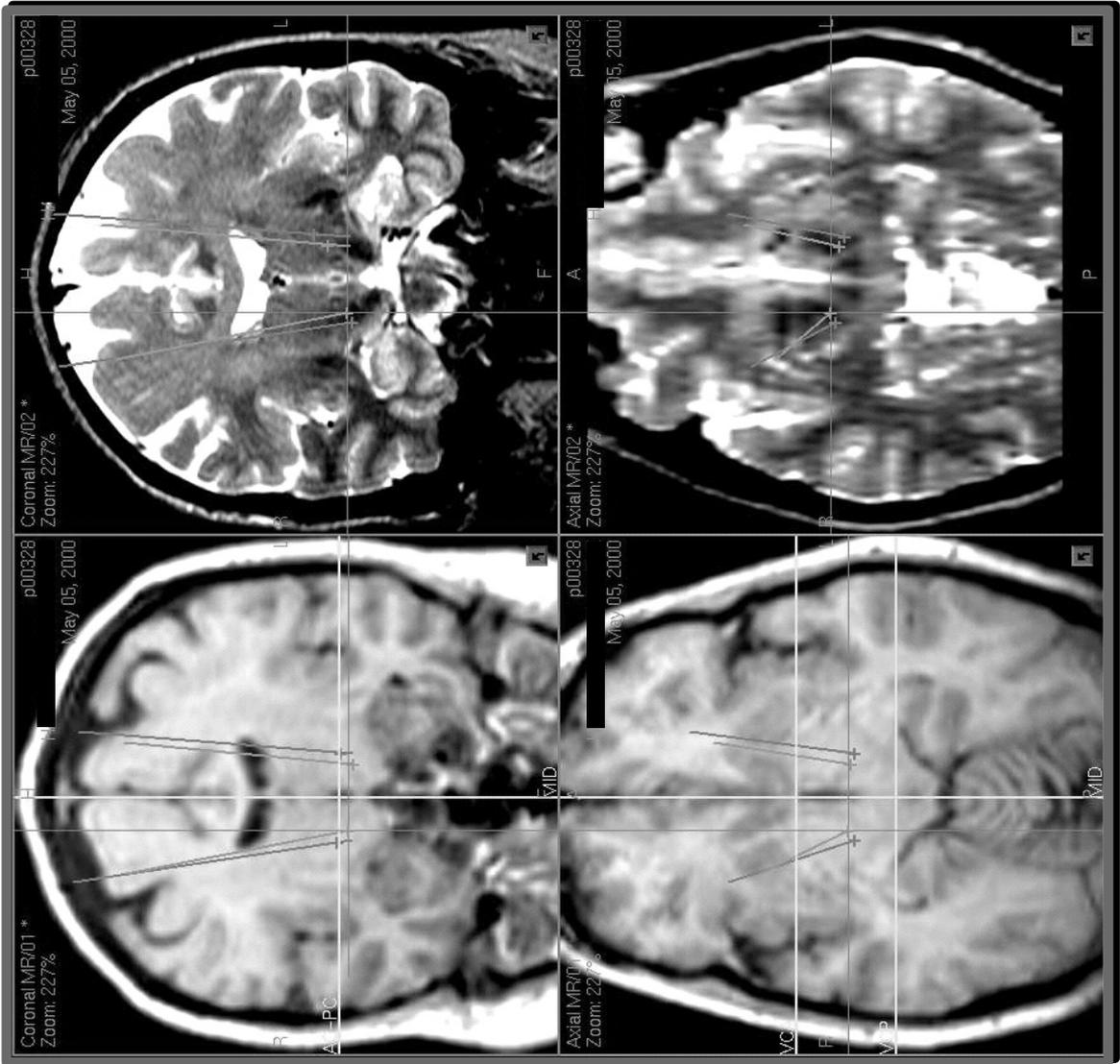


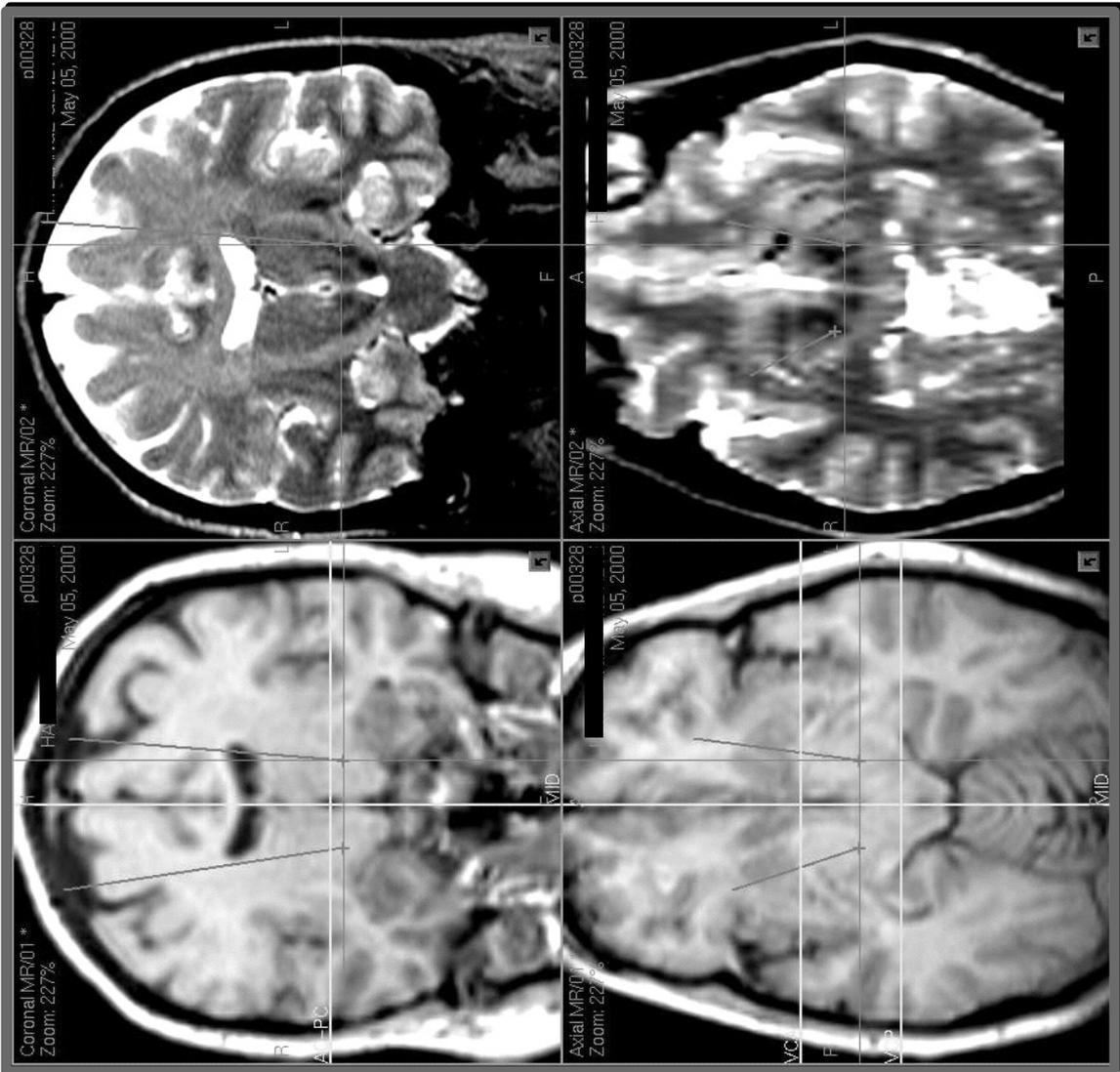
Chronic Stimulation of Subthalamic Nucleus



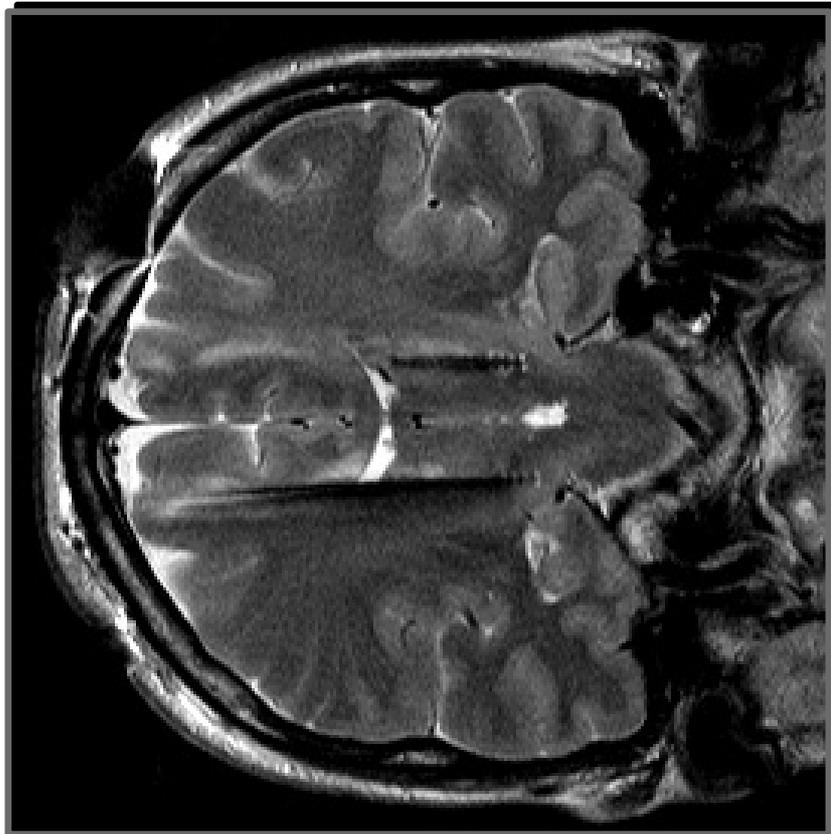
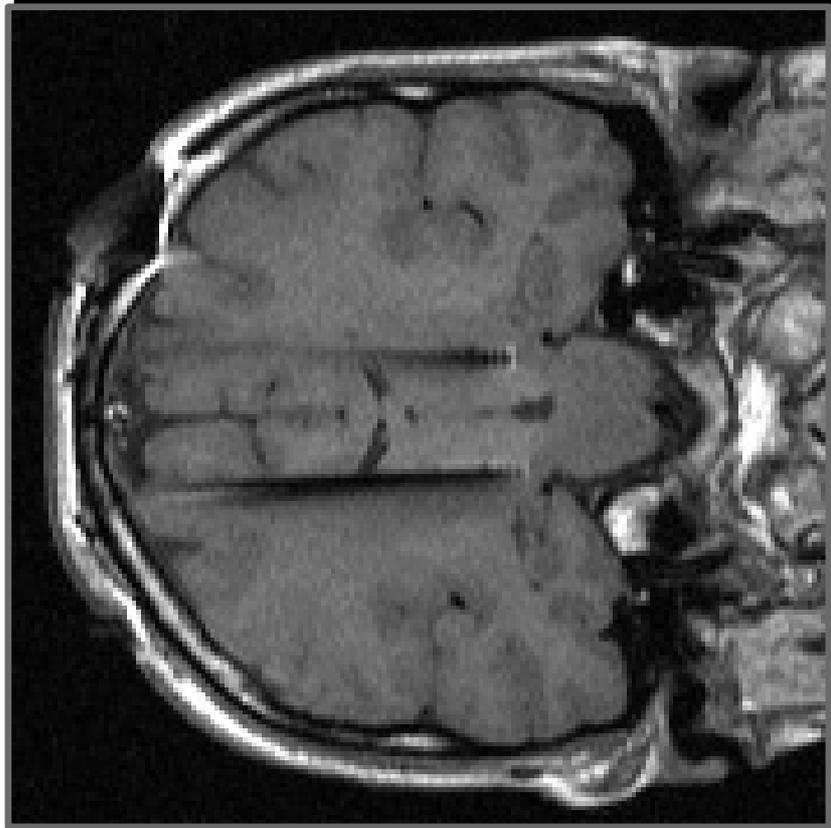


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 mid AC-AP
 V : - 3.3 mm

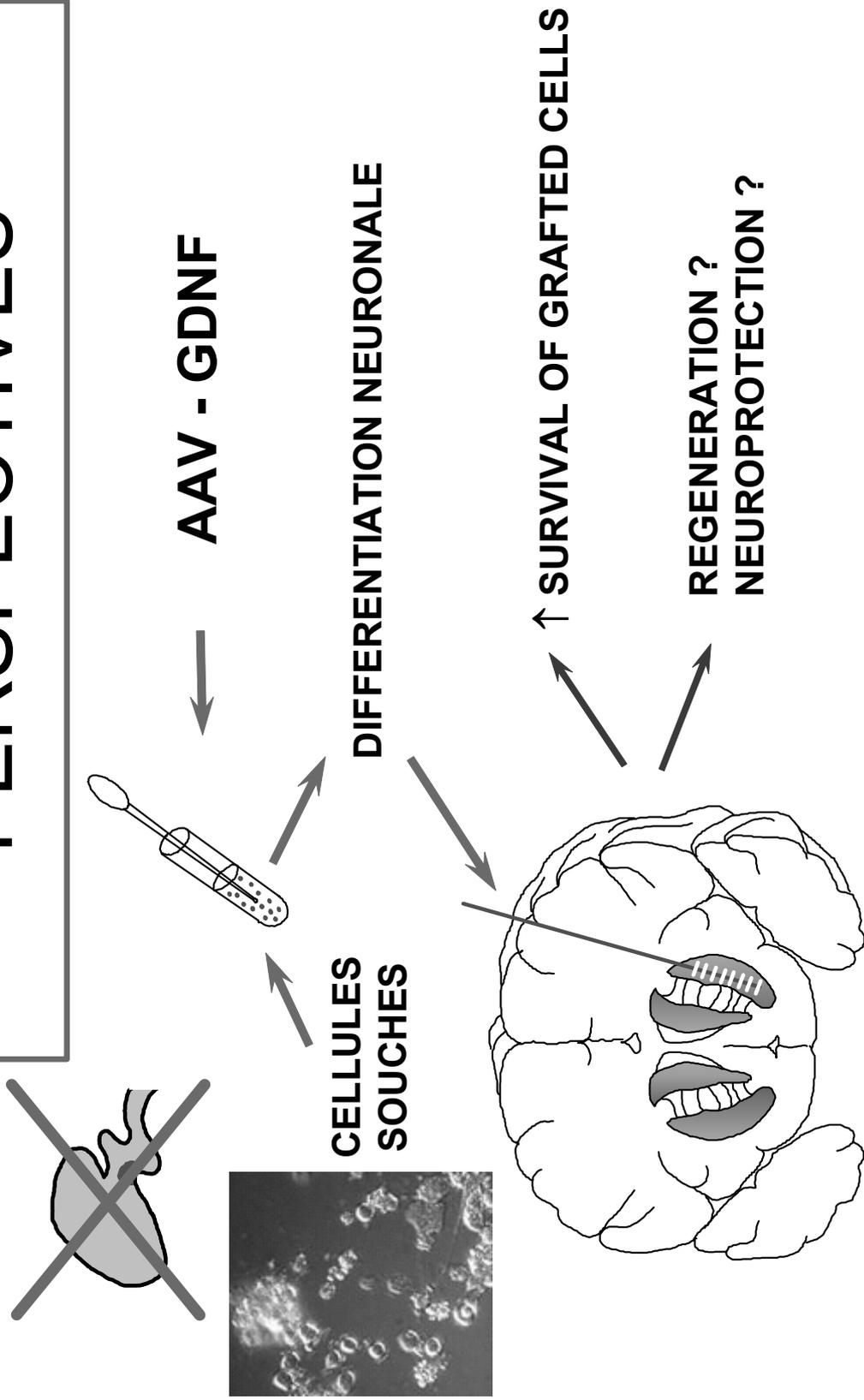




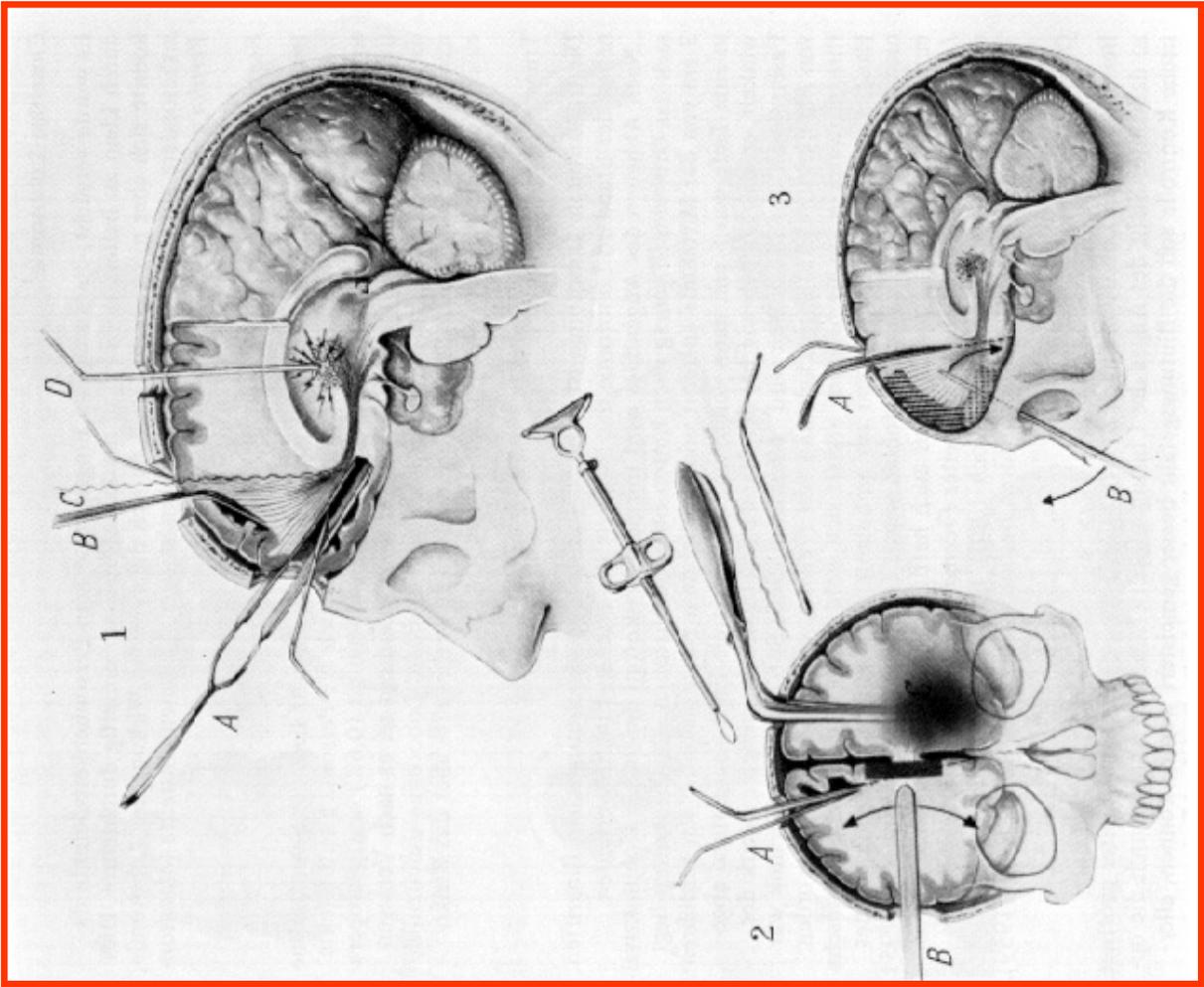
BILATERAL SUB-THALAMIC STIMULATION

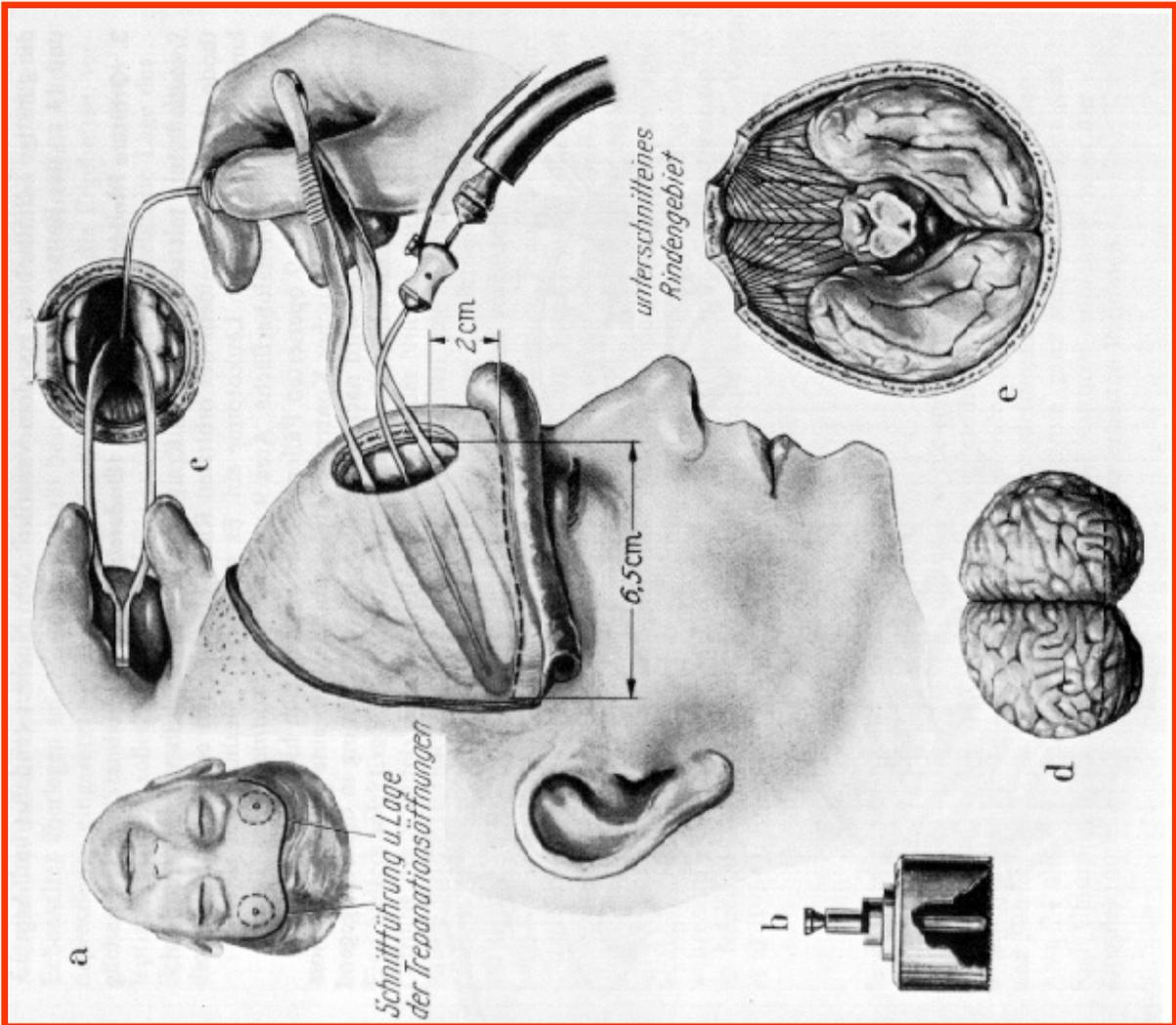


PERSPECTIVES



Psychoneurosurgery





History

« Not always does the operation succeed; and sometimes it succeeds too well, in that it abolishes the finer sentiments that have kept the sick individual within bounds of adequate behavior. What may be satisfactory for the patient may be ruinous to the family »
Freeman and Watts, 1942.

VGS STIMULATION

STIMULATION NERF VAGUE

Biological Psychiatry vol 47, number 4, Feb 2000

- Editorial by JR Rosenblum & GR Heninger: Vagus nerve stimulation for treatment-resistant depression
- Rush A.J.: Vagus nerve stimulation for treatment-resistant depressions: a multicenter study
- George MS: Vagus nerve stimulation: a new tool for brain research and therapy

FUTURE: Less invasive techniques

- **Stimulation par électrodes profondes**
Nuttin et al. Electrical stimulation in anterior limbs of internal capsules in patients with obsessive-compulsive disorder. *Lancet* 1999, 354: 1526 (letter)

Vandewalle et al. Stereotactic treatment of Gilles de la Tourette syndrome by high-frequency stimulation of thalamus. *Lancet* 1999, 353: 724 (letter)

OBESSIVE-COMPULSIVE DISORDER

Chronic stimulation of both anterior limbs
of the internal capsules

Reversible effect which is very important in
psychomodulation

Long-term Electrical Capsular Stimulation in Patients with Obsessive-Compulsive Disorder

- **Bart J. Nuttin, M.D., Ph.D.; Loes A. Gabriëls, M.D., M.Sc.Eng.; Paul R. Cosyns, M.D., Ph.D.; Björn A. Meyerson, M.D., Ph.D.; Sergej Andréewitch, M.D.; Stefan G. Sunaert, M.D.; Alex F. Maes, M.D., Ph.D.; Patrick J. Dupont, Ph.D.; Jan M. Gybels, M.D., Ph.D.; Frans Gielen, Ph.D.; Hilde G. Demeulemeester, Ph.D.**
- Department of Neurosurgery, Laboratory of Experimental Neurosurgery and Neuroanatomy, Katholieke Universiteit Leuven, Leuven, Belgium Department of Psychiatry, Universitaire Instelling Antwerpen, Antwerp, Belgium Department of Psychiatry, Universitaire Instelling Antwerpen, Antwerp, Belgium Department of Clinical Neuroscience, Section of Neurosurgery, Karolinska Institute and Hospital, Stockholm, Sweden Department of Clinical Neuroscience, Section of Psychiatry, Karolinska Institute and Hospital, Stockholm, Sweden Department of Radiology, Katholieke Universiteit Leuven, Leuven, Belgium Department of Nuclear Medicine, Katholieke Universiteit Leuven, Belgium Laboratory of Experimental Neurosurgery and Neuroanatomy, Katholieke Universiteit Leuven, Leuven, Belgium Medtronic, Inc. Department of Neurosurgery, Laboratory of Experimental Neurosurgery and Neuroanatomy, Katholieke Universiteit Leuven, Leuven, Belgium
- **Neurosurgery, 52: 1263-1274, 2003**

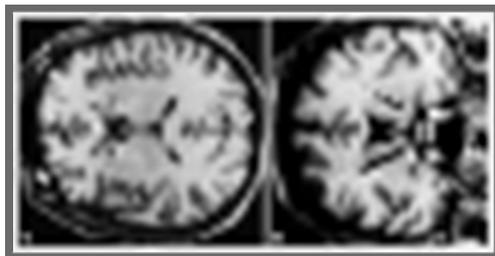
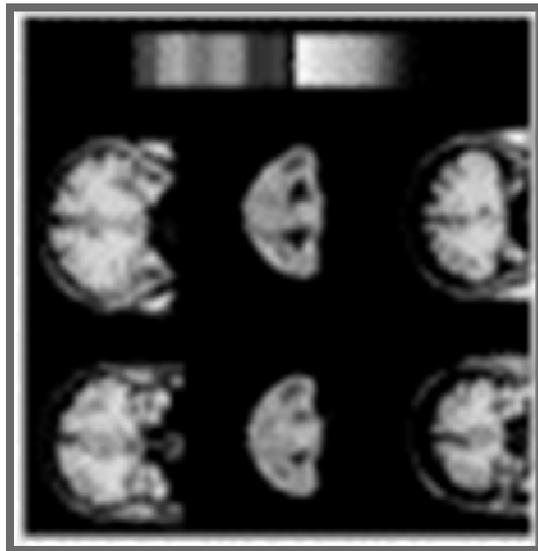
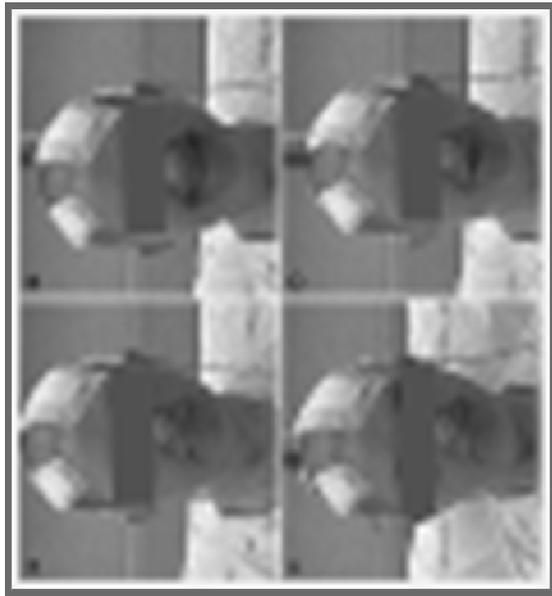
Nuttin et al.

METHODS: We stereotactically implanted quadripolar electrodes in both anterior limbs of the internal capsules into six patients with severe obsessive-compulsive disorder. Psychiatrists and psychologists performed a double-blind clinical assessment. A blinded random crossover design was used to assess four of those patients, who underwent continuous stimulation thereafter.

Nuttin et al.

- **CONCLUSION:** These observations indicate that capsular stimulation reduces core symptoms 21 months after surgery in patients with severe, long-standing, treatment-refractory obsessive-compulsive disorder. The stimulation elicited changes in regional brain activity as measured by functional magnetic resonance imaging and positron emission tomography.

(Neurosurgery 52: 1263-1274, 2003)



FUTURE

- Neurotransplantations:
 - « -restorative psychiatry »
 - « - augmentative psychomodulation »
- Functional Stereotactic Neurosurgery based on metabolic abnormalities
- Sexual disorders & criminal pedophilia??

FUTURE

Need for

- Randomized blinded prospective studies
- Strong ethical guidelines

James H. MOOR

Professor James H. Moor
Dartmouth College, USA

Biography

James Moor is a Professor of Philosophy at Dartmouth College and is an adjunct professor with The Centre for Applied Philosophy and Public Ethics (CAPPE) at the Australian National University.

He carries out research on computer ethics, philosophy of artificial intelligence, philosophy of the mind, philosophy of science, and logic.

He is the editor of the recent book *The Turing Test: The Elusive Standard of Artificial Intelligence* (Kluwer, 2004) and is the editor of the philosophical journal *Minds and Machines*.

He is the President of the International Society for Ethics and Information Technology (INSEIT) and in 2003 received the American Computing Machinery SIGCAS Making a Difference Award.

Becoming a Cyborg: Some ethical and legal implications of ICT implants

James MOOR

SUMMARY

A common complaint about ethics is that it does not keep up with technology. Implicit in the remark is the suggestion that ethics could keep up with technology if only ethicists, policy-makers, legislators, theologians, or perhaps people in general should think more about ethics. To an extent this suggestion is correct. We should do our best to anticipate technological change and put policies in place to accommodate it. However, ultimately ethics will always lag behind. We cannot foresee all technological changes and consequences accurately or precisely. We possess well-established ethical concepts and principles, but application of ethics requires interpretation and analysis of situations as well as knowledge of concepts and principles. When new technology generates novel situations, as it usually does, we need to assess afresh what we should do. Hence, we should expect that setting ethical and legal policies for ICT implants will be a dynamic enterprise. We can and should begin to frame such policies, but we must remind ourselves that the job will be ongoing. I expect ICT implants to be an evolving growth industry that will require the generation and reevaluation of ethical and legal policies for decades, if not centuries, to come. We are now only beginning on what will be a long journey.

What is special about ICT implants as opposed to implants in general or to genetic manipulation? The answer lies at what is at the heart of information and communications technology – the computer. Computers, whether they be massive machines or nanochips, are in principle universal machines. They are logically malleable both syntactically and semantically. We can alter their programs and we can redefine what their states represent. Although there are well known logical limits to computers, practically speaking the limits of their application depend largely on our imaginations. Implanting ICT devices will give humans functionality well beyond what they currently have or could ever have through traditional transplants or genetic manipulations. ICT implants provide us with colossal opportunities for improved and novel capabilities. However, they will also be a continual source of policy vacuums.

What difference does it make if the ICT device exists inside the body or outside? Isn't ICT the same wherever it occurs? The difference is that psychologically and socially we typically take our bodies as defining our boundaries as persons. We base many of our customs and laws on this assumption. As an example, consider a situation in which a patient requests a doctor to turn off a pacemaker located outside the patient's body. Such a request is generally regarded as a refusal of treatment and doctors in the United States are obligated to follow the patient's request. This is regarded as allowing the patient to die, but not killing the patient which is illegal in the US. However, now suppose the pacemaker is located inside the patient's body and he makes the same request. Is a doctor obligated to follow the patient's request? Should shifting the pacemaker from outside the patient to inside the patient make an ethical or legal difference?

What ethical principles should we follow when considering whether to allow ICT implants? Most people agree that ICT implants used for therapeutic purposes are acceptable. Hundreds of thousands of people have had cardiac pacemakers or defibrillators implanted. Significant progress is being made in developing bionic eyes. Interestingly, there has been some reluctance among some in the deaf community toward cochlear implants. This illustrates that a device that is taken to be therapeutic by some may be regarded as enhancing by others. In fact, often devices that are therapeutic have some enhancing aspects. An implant that picks up a paralysed patient's brain pattern may allow him to operate a computer, but it also gives him the unusual capacity to manipulate physical objects in the world by merely using his thought patterns.

Beyond therapeutic applications, I wish to argue that a principle of autonomy should give people a broad choice of ICT implants, even those that are clearly enhancing. However, the principle of autonomy does not override all considerations. Considerations which may trump autonomy are health, duty (for example, the duty of a parent), privacy, control, and fairness. I will discuss some examples of these limiting constraints.

Finally, many philosophers and others have argued that ethics and law should be based at least in part on human nature. However, ICT implants give us a non-biological way to alter that nature. There is, therefore, the distant but nevertheless disquieting possibility that by routinely implanting enough devices that dramatically alter our mental and physical capacities we might begin to shift how we understand ourselves and our ethical decisions.

For an elaboration of this position please see:

James H. Moor, "Should We Let Computers Get Under Our Skin?" in *The Impact of the Internet on Our Moral Lives*, Robert J. Cavalier (ed.), Albany: State University of New York Press, 2005, pp. 121-138. Also, printed in *Contemporary Moral Issues*, 3rd edition, Lawrence M. Hinman (ed.), Englewood Cliffs, NJ: Prentice-Hall, 2005.

Peter HOOGENDOORN,

President of the Dutch Parkinson Society, Den Haag, The Netherlands

Biography

Peter Hoogendoorn (1940) studied sociology at Leyden University and mass communication at the University of Amsterdam. He followed a career in advertising and became a civil servant as head of the Communications Department of the Municipality of The Hague and of The Hague Regional Authority. He published articles on public consultation, marketing research and municipal communication.

He retired in September 2001.

Peter married his wife Willy in 1965, they have two sons Rick and Bart (1967 and 1970) and two granddaughters Sophie (2000) and Wende (2004). Willy was diagnosed with Parkinson's Disease in 1988 and had a deep brain operation (in the Sub Thalamus Nucleus) in February 2000.

Since 1994 Peter has been involved in the Dutch Parkinson's Disease Patients Association. Initially as a member of the Publicity Working Group. In 1998 he was elected a member of the board and has been Chair of the association since 2000. In 2001 Peter was elected to the Administration Board of the European Parkinson's Disease Association (EPDA), of which he is Vice President at the moment.

ICT brain implants – a patient's perspective

Peter HOOGENDOORN

SUMMARY

Parkinson's Disease (PD) is a neurological degenerative affection of the basal ganglia in the inner part of the brain. Dopamine, a neurotransmitter made by the brain itself, is in insufficient supply because of the premature death of neurons in the substantia nigra. Dopamine is necessary for movement. Movement disorders are the most notable symptoms of PD but the disease has also an effect on almost every aspect of the central nervous system (CNS) and daily living: bladder control, sweating, speech, writing, dressing, washing, balance, but also mood, character change, depression, dementia and cognition.

Combating the symptoms is the only possibility; there is no cure and no prevention. For the fight against the symptoms we have medication (levodopa and dopamine agonists), but they all have side effects and in a later stage of the disease still higher doses are needed for the same effect. Eventually the drugs have a smaller and smaller effect.

Stereo tactic operations are another possibility to fight the symptoms. Destroying brain cells in some parts of the brain (thalamus, globus pallidus) by heating (coagulation) can bring relief. Nowadays doctors and patients choose mostly the Deep Brain Stimulation technique (DBS). A set of electrodes is implanted in one of the nuclei in the brain (thalamus, globus pallidus and - most of the time - the sub thalamus nucleus - STN). The electrodes are connected with pulse generators (a kind of pacemaker) implanted in the chest. When the parameters of the generators are well set and the use of the medication is adjusted, in a majority of cases a profound improvement is obtained.

However, there are also setbacks and risks. Problems can increase with speech and balance and also in the psychological sphere: apathy, depression and even suicide are serious unwanted side effects. Still it can be a good solution for most of the patients. We feel that is up to the patient to make the decision. It's the patient's choice and his quality of life. Informed consent is essential of course.

Dr. Fabienne NSANZE

MD, Trainee at the EGE Secretariat of the European Group on Ethics in Science and New Technologies to the European Commission (EGE)

Biography

Born in Tournai in 1976, Fabienne Nsanze completed with honours her medical studies at the Leuven Catholic University in Brussels, Belgium in 2001.

She has considerable experience in Computer Science, and has implemented a project in the field of Education and Information and Communication Technologies (ICTs) at the Leuven Catholic University (UCL), Louvain-La-Neuve, Belgium. In May 2003, she presented her research "The Virtual Patient" at the 20th International Congress of AIPU (Association Internationale de Pédagogie Universitaire) on «ICTs and Teaching», Sherbrooke, Canada.

Fabienne Nsanze has a strong interest in Public Health and Development Cooperation, and holds a University Diploma on the Methods and Practices in Epidemiology, in the Institute of Public Health, Epidemiology and Development of the University of Bordeaux II, France.

She was also trained in the «Methods of Planning in the Health Sectors», at the School of Public Health of the Free University of Brussels (ULB), Brussels, Belgium, as well as on interdisciplinary approaches to Development Cooperation, from the Coopération Technique Belge (CTB), Brussels, Belgium.

At the present time, she holds a traineeship appointment (October 2004 – February 2005) within the Secretariat of the European Group on Ethics in Science and New Technologies, where she has written the scientific background for the EGE's forthcoming Opinion N° 20 on "*ICT implants in the Human Body*". She is also preparing a short paper on stem cell research for possible future use by the EGE.

ICT implants in the human body : a review

21 December 2004

Fabienne NSANZE

Introduction

Present day uses such as heart pacemakers, cochlear implants and neurostimulators are not the focus of this paper. Rather, attention is given to implants that use computer technology either for control/surveillance or enhancement purposes.

Apart from one example (the subdermal RFID device, Verichip™, see below), all of these ICT implantations are active implantable devices for "functional electrical stimulation". They partially replace the neural functions of the body by means of electrodes that establish a direct contact to nerves.

http://www.medics-network.com/download/schneidersteiglitz_jf04.pdf

"Over the last 50 years, we have seen evolution of pacemaker technologies, as an accepted form of intrusion into human body." This is confirmed by the recent U.S. Food and Drug Administration approval of implantable ID chips in humans, for security, financial and personal identification or safety applications.

Besides medical purposes, *"for [healthy] beneficiaries, implant technologies involve possibly some future advantages, like rapid math, memory capacity or communication by thought."*

[quoted from http://www.unido.org/file-storage/download/?file_id=10499]

Categorisation of Implantable Devices

Implantable devices can be categorised as **medical** or **non-medical** devices, both either **passive** or **active** devices.

✚ Implantable medical devices

Most passive implants are structural devices such as artificial joints, vascular grafts and artificial valves. On the other hand, active implantable devices require power to replace or augment an organ's function or to treat an associated disease.

The **Council Directive 90/385/EEC on active implantable medical devices** gives the following definition: "active implantable medical device" means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

The "device" definition within the meaning of Directive 90/385/EEC relates to a product intended by the manufacturer for a medical purpose "whether used alone or in combination, together with any accessories or software for its proper functioning". The medical purpose may be achieved either by a "stand alone device" or as a result of several devices acting each in combination with the other as part of a system.

✚ Implantable non-medical devices

An example of a passive device is the radio frequency identification (RFID) device. Active devices may use electrical impulses to interact with the human's nervous system.

PART I: Implantable devices already available on the market

This first section contains information about implants in the human body that are available in commercial form and have been researched, in some cases, for decades.

1. Current active medical devices

- ✚ Cardiovascular pacers for patients with conduction disorders or heart failure
- ✚ Cochlear and brainstem implants for patients with hearing disorders
- ✚ Implantable programmable drug delivery pumps
 - ✓ **Intrathecal administration of Baclofen** for patients with Multiple Sclerosis with severe spasticity
 - ✓ **Insulin pump** for Diabetes
 - ✓ **Neuroleptic /antipsychotic drugs**, the so-called "psychiatric implants"

✚ Implantable Neurostimulation Devices

- ✓ **Spinal cord stimulation** for chronic pain management
- ✓ **Sacral nerve stimulation** for control of urinary incontinence
- ✓ **Vagus nerve stimulation (VNS)** for **seizure control in epilepsy** and **mood control in severe depression cases**: the small generator and lead are surgically attached to the rib cage, with the wires travelling under the skin up to the neck and wrapping around the left Vagus nerve. From there the generator sends electrical signals via the Vagus nerve to the brain.

The VNS therapy system, developed by Cyberonics, Texas, has been widely used to reduce epileptic seizures since 1997 in the US.

In July 2004, the US Food and Drug Administration approved the implantable VNS therapy as a treatment for untreatable chronic depression.

According to studies presented by Cyberonics, "*stimulation of the left Vagus nerve produces widespread and bilateral effects in the parts of the brain implicated in epilepsy, depression, anxiety and memory.*"

<http://usmedicine.com/article.cfm?articleID=912&issueID=64>

(Accessed on 29 November 2004)

✚ Deep brain (thalamic) stimulation

- ✓ for tremor control in patients with **Parkinson's disease**: "On April 1998, a breakthrough therapy (Activa® Therapy, Medtronic, Inc; <http://www.medtronic.com>) combating the symptoms of disabling Parkinson's disease, obtained the CE mark and was released on the European Union market. This technology involves mild electrical

stimulation of the *globus pallidus* or the subthalamic regions of the brain to control the major symptoms of Parkinson's – stiffness of limbs and joints, slowness or absence of movement, impaired balance and co-ordination, in addition to the characteristic involuntary rhythmic shaking (tremor). More than one million people across Europe are estimated to suffer from Parkinson's disease. Patients whose disease is not controlled by medications have difficulty in performing the basic tasks of daily life."

The implantable system includes a neurostimulator connected to a lead with four tiny electrodes near the tip. "The neurostimulator, which contains a battery and a microelectronic circuitry, is placed under the skin near the collarbone and provides the mild electrical stimulation that is carried through the lead to the electrodes implanted deep in the brain.

The level of stimulation can be adjusted externally to meet individual patient needs.

The therapy is completely reversible. The estimated longevity of the implanted battery is three to five years, with 16 hours of use per day."

<http://www.eucomed.be/docs/MT-IP-parkinson%60s%20disease.pdf> (Accessed on 25 October 25 2004)

- ✓ for **essential tremor**: Patients with essential tremor have no symptom other than tremor, which may occur in their hands, head, legs, trunk or voice. As for patients with Parkinson's disease, they can be helped thanks to the deep brain stimulation therapy.

2. Current identification and location devices

✚ Introduction: microchip devices might have three embodiments

- ✓ "**Read-Only**: this is the simplest form of devices that have a read-only character, similar to that now used for identification of animals. Even this most basic form would have numerous applications, for example, to identify Alzheimer's patients, children and the unconscious. A broader use would be as a sort of national identification card, based upon the identifying number carried on the microchip."
- ✓ "**Read-Write**: this type of microchip would be capable of carrying a set of information which could be expanded as necessary. It allows the storage of data and is programmable at distance. For example, when the microchip carries a person's medical history and the history evolves, the subsequent information could also be added to the microchip without the necessity of removing the implanted chip. It could also facilitate and record financial transactions. The third important set of information that a read-write microchip could carry would be criminal records."

At present, the Verichip™ (see below), for example, includes a memory that holds 128 characters only. Larger microchips, and highly specialized and more sophisticated ones, are underway.

- ✓ **“Read-Write with tracking capabilities:** in addition to the read-write capabilities described above, a device can also emit a radio signal which could be tracked. Applications would again be numerous as evidenced by the less advanced technologies already in existence. Such a device needs a power source, that has to be miniaturized before being implantable. If a microchip implant had tracking capabilities, it would be superior to the currently available electronic tether because it would not require the telephone as an adjunct. With a microchip implant, constant monitoring would be possible. If each chip emitted a signal of a unique identifying frequency, implanted individuals could be tracked by simply dialling up the correct signal. Because the receiver is mobile, the tagged individual can be tracked anywhere. “

www.fplc.edu/risk/vol8/fall/ramesh.htm

(Accessed on 24 October 24 2004)

✚ RFID devices

Millions of Radio Frequency Identification Device (RFID) tags have been sold since the early 1980s. They are used for livestock, pet, laboratory animals, and endangered-species identification.

This technology contains no chemical or battery. The chip never runs down and has a life expectancy of 20 years.

How it works.

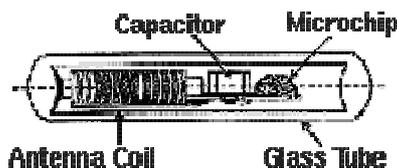
The chip is an ID tag which is inert/passive (not independently powered). When radio-frequency energy passes from a scanner, it energizes the chip, which then emits a radio-frequency signal transmitting the chip's information to the reader, and which in turn links with a database.

How the information is used is determined by the administrators of the security systems and databases.

✚ VeriChip™ or the “human bar coding”

VeriChip™ is a subdermal RFID device, about the size of a grain of rice, commercialized by Applied Digital Solutions (ADS), one US-based company.

What is its composition?



“The RFID implant consists of a microchip, an antenna coil and a capacitor all enclosed within a sealed glass tube. An anti-migration cap surrounds the glass tube to inhibit movement of the RFID within the tissue where the device is placed.”

www.angelfire.com/hi2/gracebelievers/microchip_implants_apr2003.pdf

The idea for employing the tags to identify humans came after the horror of the 11 September 2001 attacks on the World Trade Centre in New York.

FDA appears to have carried out a preliminary risk assessment (using the company's safety testing data) in giving marketing approval for this device (<http://www.sec.gov/Archives/edgar/data/924642/000106880004000587/ex99p2.txt>).

The letter of approval lists all the identified hazards and indicates that there is "reasonable assurance of the safety" of the device for the intended use (as a subcutaneous RFID). The potential risks to health identified by FDA include "adverse tissue reaction, migration of implanted transponder, failure of implanted transponder, electromagnetic interference, electrical hazards, magnetic resonance imaging (MRI) incompatibility and needle stick."

Current application of the VeriChip™

According to ADS, VeriChip™ provides security for:

- ✓ Medical records and healthcare information (blood type, potential allergies and medical history)
- ✓ Personal information/identity
- ✓ Financial information (secondary verification)

Besides these areas, the extended applications include public transportation security, access to sensitive buildings or installations and tracking down of people on parole, ex-convicts, criminals, etc.

Right now, a person has to stand within a few feet of a scanner for the tag to "wake up". Thus, the tags can be used to follow someone's steps only when they are near scanners. Consequently, the VeriChip™ is not for the moment an implantable GPS device (see below).

At present, the implantation is purely voluntary.

After Mexico, Colombia, Argentine, Brazil, Chilli, Paraguay and Uruguay, and following a broad advertisement tour in North America, the Verichip™ is now arriving in Europe as well.

1. In **South America**, faced with the huge problem of kidnappings, the VeriChip™ is being marketed mainly to identify kidnapped children or adults.
2. **Italy**: On April 2004, the Ministry of Health and the Instituto Nazionale Lazzaro Spallanzani Hospital started a study to evaluate the VeriMed™ system's impact on improving the quality of care provided to patients
3. **England**: Surge IT Solutions intends to use the VeriChip™ technology for secure building access for government installations, educational facilities, and various identification applications.

3. Current commodity devices

✚ Credit card implant

In the Baja Beach Club (in **Spain** and **The Netherlands**), people use the VeriChip™ much like a smartcard to speed drink orders and payment. <http://www.baja.nl>. (Accessed on 24 October 2004).

✚ Remote-control Orgasm Implant

For the electronic orgasm device to work, a physician would implant electrodes into the spine and a small signal generator in the skin under the buttocks. A patient would then control the sensation with a handheld remote control.

<http://www.newscientist.com/news/news.jsp?id=ns9999397>

(Accessed on 8 December 2004)

PART II: Implantable devices UNDER DEVELOPMENT

4. Future active medical devices

✚ MEMS (Micro Electro-Mechanical System)

The micro-electro mechanical systems device (MEMS) is an implantable micro-sensor that can send data to a hand-held receiver outside the body, alerting doctors to a potential medical crisis, without using any wires or batteries.

✚ Brain prosthesis

- ✓ **artificial hippocampus:** an implantable brain chip that could restore or enhance memory.

The hippocampus plays a key role in the laying down of memories. Unlike devices such as cochlear implants, which merely stimulate brain activity, this chip implant will perform the same processes as the damaged part of the brain it is replacing. It will be a way to help people who have suffered brain damage due to stroke, epilepsy or Alzheimer's disease.

There are several research teams in Europe and the US that are currently working on so-called neural-silicon hybrid chips.

Theodore Berger at the University of Southern California in Los Angeles is emulating the neurons' behaviour on slices of rat brain bombarded by electrical input. Now, its silicon microcircuit is about to be tested in live rats.

Berger and his team have taken nearly ten years to develop their current chip models of 100 neurons. However it will need at least a 10,000-neuron chip model for implantation in a primate hippocampus. <http://www.newscientist.com/news/news.jsp?id=ns99993488>

- ✓ **Cortical implant** for the blind:

Electrodes implanted in the visually responsive areas of the brain would supply vision to the profoundly blind. Cortical implants require brain surgery and the pneumatic insertion of electrodes into the brain to penetrate the visual cortex and produce highly localized stimulation. <http://www.spectrum.ieee.org/publicaccess/9605teaser/9605vis6.html>

- ✚ Ocular implant : implantation of an electrode array on the retina; retinal implants avoid brain surgery and link a camera in eyeglass frames via laser diodes to a healthy optic nerve and nerves to the retina

- ✚ Brain-computer interfaces or direct brain control

The technologies involved here are communication technologies; they take information from the brain and **externalize** it.

There are **internalizing** technologies (cochlear or optic-nerve implants) whose purpose is to take information from the outside and provide individual access to it. These two technologies will eventually come together to form **interactive** technologies which would allow input-output interactions.

A US-based company called Cyberkinetics, specialized in neurotechnologies wiring computers to human brain, has received Food and Drug Administration approval in April 2004 for a clinical trial of the BrainGate™ Neural Interface System. If successful, this four-square-millimeter chip could allow paralyzed people to send computer commands by thought.

How does the BrainGate™ work?

"The neural signals are interpreted by the System and a cursor is shown to the user on a computer screen that provides an alternate "BrainGate pathway". Then, the user can use that cursor to control the computer, just as a mouse is used."

<http://www.cyberkineticsinc.com>

Although human studies show the feasibility of using brain signals to command and control external devices, the researchers emphasize that many years of development and clinical testing will be required before such devices - including "neuroprosthetic" limbs for paralyzed people, become available.

At the same time, because of what most people mean by brain-computer interfaces (BCI), there is also a lot of work done to create non-invasive BCIs.

✚ Neurofeedback

Neurofeedback is a learning procedure – a kind of exercise for the brain - that is already widely used for conditions such as depression, epilepsy, sleep disorders and many others.

Several companies are now looking to find a way to increase mental well being and mental prowess using brain-computer interface **and** neurofeedback techniques.

This process involves connecting electrical impulses from the user's brain to the computer and back again, creating a feedback loop between the computer and the user. Neurofeedback allows the computer to interact with the user through electrical impulses.

Such devices induce brain states that are similar to those seen on an EEG when one is learning or concentrating on a task. By artificially inducing these brain states researchers hope to provide a means of personal control of ones own mood and emotional state.

5. Future personal tracking devices

✚ Subdermal GPS Personal Location Device

Such a device would allow an individual with a scanner to pinpoint someone's position on the globe.

In May 2003, Applied Digital Solutions (ADS) claimed that a prototype implantable GPS tracking device had been successfully tested. However, technical experts are questioning whether the system could really work. The disc-shaped "personal location device"

measures 6.35 centimetres in diameter and 1.27 centimetres in depth - roughly the same size as a pace-maker. <http://www.adsx.com/news/2003/051303.html>

Currently it consists of an antenna to receive signals from the satellite constellation that comprises the Global Positioning System and an induction-based power-recharging system. The latter should make it possible to recharge the device's batteries from outside the user's body. Eventually the device will need to connect to a cell phone network if it is to relay the satellite-determined position of its host to another person.

ADS says it should be possible to shrink the overall size of the device by at least half.

This GPS monitoring could be used for several purposes, such as for example,

- in case of Medical emergencies
 - ✓ Heart attack
 - ✓ Epilepsy
 - ✓ Diabetes
- for identification and location purposes
 - ✓ People in high risk occupations
 - ✓ Children
 - ✓ Stalkers
 - ✓ Suspected terrorists.

In England, Kevin Warwick, a professor at Reading University, is also developing an implantable GPS microchip. <http://www.kevinwarwick.com>

6. Future enhancement or commodity devices

According to Ellen McGee "computer scientists predict that within the next twenty years neural interfaces will be designed that will not only increase the dynamic range of senses, but will also enhance memory and enable "cyberthink" — invisible communication with others." [quoted from <http://www.bu.edu/wcp/Papers/Bioe/BioeMcGe.htm>, 4 April 1999, accessed on 18 October 2004]

✚ Prosthetic cortical implant (intelligence or sensory "amplifiers")

The user's visual cortex will receive stimulation from a computer based either on what a camera sees or based on an artificial "window" interface.

✚ Audio tooth implant or tooth phone

Described in 2002, the Audio tooth implant, designed by James Auger, still only exists in concept form.

A micro-vibration device and a wireless low frequency receiver are implanted in the tooth during routine dental surgery. The tooth communicates with an array of digital devices, such as mobile telephones, radio and computers.

Sound information is transferred from the tooth into the inner ear by bone transduction. Sound reception is totally discreet enabling information to be received anywhere at anytime.

<http://www.scienceandsociety.co.uk/results.asp?image=10328750&wwwflag=&imagepos=2>

. Accessed on 26 November 2004

Artificial hippocampus: as mentioned above, this implantable brain chip could enhance memory.

Main Points Arising from the Discussion

ROUNDTABLE
Ethical aspects of ICT implants in the human body

The Discussion

Organised by the European Group on Ethics in Science and New Technologies

The three presentations were followed by a session of questions and answers as well as a wide ranging and lively discussion. Some of the key points from the discussion are summarised below.

- A critical discussion took place regarding **autonomy**. Different views were expressed, ranging from those who thought that adults could do whatever they wanted provided they did no harm to others, to those who thought that some individuals need controlling and that therefore complete autonomy is not desirable. Mention was made of possible military use of implants for tracking purposes (dual use). This is still at the early research stage but could become a serious issue in the future. In spite of the wide range of views there was nevertheless a consensus that implants could represent a threat to autonomy and that some form of guidelines for **enhancement** were needed.
- Another issue which was mentioned on several occasions concerned **informed consent**. Implants can generate undesired side effects and it is commonly agreed that informed consent is necessary prior to any decision to use implants. Nevertheless, because implants can indeed change/improve the capacities of individuals, it was debated whether in some cases informed consent should also be sought after the person had been implanted and therefore more in possession of “full faculties”. There is a dividing line between “care” and “autonomy” and clearly consent for implant procedures is necessary but it may not be sufficient where brain implants are concerned.
- The question of the impact of ICT implants on **public health** was discussed. Although it is obvious that some kinds of ICT based monitoring could be useful, several participants were concerned that the public health drive might accelerate the use of implants to “do societal good”. The example of obesity was mentioned, as it was discovered by chance that the part of the brain regulating obesity can be stimulated and controlled with electrodes. Cost-effectiveness is a condition *sine qua non* when public health is concerned and surely in the case of obesity the criteria of cost-effectiveness would be fulfilled leading to pressures for its use. Another concern which arose in this context was the uncertainty that the initial objective of the monitoring remains the same over time. There is perhaps a moral obligation to “offer” but not to “compel” the use of a “beneficial” implant – say for obesity.
- The **reversibility** of ICT implants was mentioned on several occasions. Indeed, it is considered as an advantage as opposed to brain surgery or genetic enhancement.
- Amongst possible enhancements that might be possible through ICT implants are **memory chips** to augment the memory capacity. This possibility raised strong concerns, notably because if it would help improve the memory capacity there would also be a risk that the memory keeps things that are not desirable to retain. This poses strong ethical concerns and may be on the edge of “what should be allowed” in the view of one participant.

- The ethical question of **testing** ICT implants in the **great apes** was raised. In response the experts stressed the complexity and sensitivity of this issue and the wide variation in approaches between the Member States. It was emphasized that the question could only be approached with complete transparency. The scientific and medical evidence and interest had to be presented together with the ethical guidelines.
- The issues of **fairness** and **technological drives** were debated but without clear conclusions. It was obvious to the participants that the field needs regulation and that perhaps implantable devices should be regulated in the same way as drugs when the medical goal is the same. A number of areas of legislation could be involved (medical devices, privacy, telecoms, etc.) and an analysis of what is missing would be valuable. We should not allow this technology to control our lives (cf. the Verichip).

Written Comments Received

*on issues discussed and raised
at the EGE Roundtable on the
Ethical aspects of ICT implants
in the human body*



Comments
on issues discussed and raised at the EGE ROUNDTABLE ON
the Ethical aspects of ICT implants in the human body

- Health Care / Medical Treatment Issues -

Helen BARKER, LL.M.,
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A. Informed Consent

As with any other kind of medical treatment or medical procedure, ICT implants should only be used where there has been a free/voluntary and fully informed consent by the patient or someone authorised to consent on their behalf.

This requirement raises a number of ethical and legal problems and may not be satisfied in all cases.

- 1) As yet, most ICT implants in the human body are still experimental and subject to ongoing research and monitoring in respect of their use and effectiveness. Consequently, the use of ICT implants, for both therapeutic and non-therapeutic purposes, should not only be governed by and conform to national and European law, conventions, codes of practice and codes of ethics, but should also be governed by and conform to international conventions and codes of ethics, such as the Declaration of Helsinki 1964.

ICT implants should not normally be used in randomised trials, as the requirements of informed consent are particularly difficult to satisfy for randomisation.

- 2) Some patients, or particular types of patient, may be unable to give informed consent, or may be especially vulnerable and, therefore, their consent may not be truly voluntary.

a. Incompetent Patients

ICT implants give rise to particular ethical and legal problems when used in the care and treatment of incompetent patients. Clearly, incompetent patients are unable to give consent to medical procedures or treatment and some form of proxy consent is, therefore, necessary. Key issues here are: 'on what basis should proxy consent be given and by whom'? Such decisions are usually made either on the basis of the 'best interests' of the patient, or on the basis of 'substituted judgment'.

Both tests import some evaluation of the patient's quality of life, but this is a concept that continues to trouble lawyers and ethicists: how should quality of life be measured, especially when the patient personally is unable to contribute to the debate? Furthermore, it is now generally acknowledged that 'best interests' may be wider than just best 'medical' interests and that substituted judgment may not be an appropriate test for decision making where a patient has never had capacity.

As with other sensitive or controversial areas of medical treatment, health care and personal welfare, proxy consent for ICT implants may need to be qualified or subject to certain limitations and restrictions.

b. Changes in Circumstances

Certain patients may have given a so-called informed consent at some stage prior to the procedure in question, but their condition may have deteriorated to such an extent that their consent can no longer be relied on, or may be invalidated by later events. This kind of situation was alluded to by Peter Hoogendoorn when he gave the example of a patient suffering from Parkinson's Disease, whose condition must have degenerated to a certain degree before an ICT implant would be considered as a means of combating the patient's symptoms. In this kind of situation, either proxy consent must be obtained or the patient must be denied the treatment.

c. Vulnerable Patients

Certain types of patient, or specific groups (eg. patients with mental health problems, prisoners) may be especially vulnerable and their consent may not be truly voluntary. People facing a long period of confinement may readily agree to anything that appears to offer the prospect of a 'cure' or early release.

In all cases, there must be an exit. Where consent has been given, it must be possible to withdraw that consent at any time. This would not be possible if the ICT implant or the effects of it were irreversible.

B. Finding Things by Serendipity

Where ICT implants are being used for one or more particular purposes, the incidental or accidental discovery of other potential applications/treatments must not be exploited.

Any additional or alternative uses of the ICT implant must be subject to the same requirements of informed consent as those governing the original procedure or treatment. The individual patient cannot be given additional treatment or be subjected to additional procedures for which a valid consent has not been obtained.

There is a further risk here of ICT implants being used in respect of a wider class of persons, rather than just the individual patient. The incidental/accidental discovery of the control or treatment of illnesses or health problems which may have public safety, public health or health care cost implications provides a good example of the potential for abuse and exploitation. Here again, the use of ICT implants must be governed by the same ethical and legal principles as those which govern the use of such implants in respect of individual patients.

ICT implants should not be used as a means of social control. In the UK, we already have examples of health care and health care law being used in this way (e.g. mental health treatment and mental health laws). Whether in relation to an individual patient, or a wider class of patients or persons, non-consensual treatment or compulsion can only rarely, and only in the most extreme circumstances, be justified. Compulsion must be based on clear, objective medical criteria and there must be appropriate procedural safeguards.

C. Risks/Side Effects

Because of the relatively recent use of, and experimental nature of, ICT implants in the human body, we may not yet be fully aware of possible risks and side effects. Even when ICT implants are reversible, the effects of these may not be; which clearly also has implications in relation to the requirement of informed consent.

The argument put forward by Professor Jacques Brotchi that ICT implants (including deep brain implants) are less invasive forms of 'treatment' than other accepted techniques, such as psychosurgery,

are not entirely convincing. Clearly, the more invasive a treatment or procedure, the greater the ethical problems. However, whilst ICT implants may be less destructive initially, and possibly in the short term, than other treatments or procedures, if we are not yet fully apprised of the risks and side effects how can we be sure that such techniques and procedures are less invasive or indeed reversible?

D. Therapy versus Enhancement

The distinction between therapy and enhancement is often difficult to define and the boundary between them is, therefore, difficult to draw. Dr James Moor's discussion of the controversy within the deaf community on the issue of cochlear implants is an excellent example of the problems encountered in attempting to draw a line between therapy and enhancement.

If one adopts the classic definition that 'therapeutic' means of benefit to the patient, then enhancing implants could also be covered by this definition. The distinction between therapy and enhancement must, therefore, lie in the fact that therapy is concerned with maintaining, repairing or restoring body parts or functions which the patient previously had or enjoyed, whilst enhancement is concerned with the creation, improvement or betterment of body parts or functions which were previously not present or are not otherwise damaged or malfunctioning. Ethical issues are raised by both therapeutic and non-therapeutic or enhancing applications of ICT implants although, generally, the former will give rise to fewer concerns than the latter.

1) The key ethical issues in relation to therapeutic implants are, as noted above, the consent requirements, which must be satisfied, and the risks and side effects of the application or treatment, which must be weighed against the potential benefit(s) of the treatment or application. Caution needs to be exercised, however, as patients who agree to ICT implants for therapeutic purposes may be especially vulnerable and willing to consent in the hope of alleviating or curing their condition.

2) A number of ethical issues are raised by enhancing implants, not least those relating to human dignity, personal freedom, risk of harm to the individual implanted and risk of harm to others and to the wider community and society.

Conflicting interests may arise here (although human dignity and personal freedom are not necessarily mutually exclusive nor necessarily conflicting principles).

An individual may freely agree to an enhancing implant, but should they be allowed to? Do we as a society have a right to override that individual's freedom on the grounds of a higher and wider moral duty to others? On the other hand, if we deny an individual this freedom, is this not just a different or inverse form of compulsion. For example, we might not introduce a programme of compulsory castration for all male sex offenders, but we might allow an individual offender to be castrated if he chose this option himself on the basis that it would make him a better person. That said, if we did allow it, and justified it on the ground of individual freedom, would it make it right?

Law has always imposed certain restrictions on people's personal freedom and, like law, ethics has a role to play here. Personal freedom cannot be the sole or main criterion for allowing enhancing implants (or indeed for allowing certain types of therapeutic implants). People cannot exercise complete freedom, because an individual's freedom has to be balanced against the rights of other individuals and against the collective rights of society as a whole.

3) The distinction between therapy and enhancement is particularly important in the contexts of human autonomy and 'normality'.

a) Human Autonomy

If one subscribes to the view that human autonomy involves more than merely the ability to carry out certain functions, then ICT implants, whether therapeutic or enhancing, do not necessarily facilitate or increase human autonomy.

If autonomy embraces the capacity to think, reason, decide and act freely and independently on the basis of such thought, reasoning and decision, then actions, functions or behaviour which are activated or stimulated by ICT implants may be nothing more than automatic. This does not make an individual more autonomous, but may merely make them an automaton. The example given by Dr James Moor of the paralysed patient who has a chip implanted that allows them to control the lights provides a good illustration of this: while this chip might give this individual a certain degree of independence, it might not give them true autonomy. Likewise, Dr Jacques Brotchi's example of a depressed patient who can be made to smile by brain stimulation is another example of automatic behaviour, rather than of autonomy.

b) Normality

The key question here is: 'what is meant by normality'?

Even if 'normality' can be defined or measured, the concept of normality does not assist us in determining whether an ICT implant is being used for therapy or enhancement.

The Oxford dictionary defines 'normal' as an adjective meaning 'conforming to standard' and defines 'standard' as a noun meaning 'an object or quality or measure to which others should conform or against which others are judged'. However, 'normal' is also defined as including 'usual'. Usual is defined as something which 'commonly occurs'.

Clearly, if we substitute 'usual' for 'normal' then people do not have to conform to, or be measured against, a standard. Instead, some people will have, or display, certain commonly occurring characteristics, which may not occur in others. In this way, some people may be unusual, but not abnormal. Thus, any ICT implant which operates to bring people within what may be called the 'range of normality' would be enhancing, rather than therapeutic.

This line of argument is similar to that which is often mooted in relation to the concept of 'disability'. Are people really disabled or are they simply lacking certain abilities? (Again, Dr James Moor cites the example of the diverging views amongst the deaf community as to whether or not deafness is a disability).

Even if we prefer to use traditional terminology such as 'normal' and 'disabled', we are still faced with the issue of whether ICT implants are therapeutic or enhancing and whether they should be used to repair, correct or change people who do not conform to our perceptions of 'normal'. This means we must also ask ourselves the following question: 'what is wrong with being disabled'?

Society seems to be increasingly uncomfortable or uneasy with the concept of disability. This is so, despite a population that is more aware of and more educated about disability and in spite of equality laws aimed specifically at eradicating discrimination towards disabled persons.

Many disabled people function adequately within their own community or culture. Correcting disabilities or abnormalities is not the only, nor necessarily the best way of overcoming them.

All too often, disability is associated with issues of 'quality of life', but these are not inextricably linked. The only appropriate or true test for measuring a person's quality of life is a subjective one, because only the individual in question can decide what quality or value their life has for them. In cases where treatment decisions are made in respect of incompetent patients using the quality of life criterion, they are usually made in accordance with so-called objective criteria, without the individual patient being involved in that decision-making process.

Special caution is needed in the use of ICT implants which have the potential or capability to change people's physical characteristics, mental characteristics or personality. It is human diversity that makes people human beings and human beings that make society.

ICT implants should not be used for eugenic practices or to create a 'better' or more 'perfect' race.

E. Privacy, Confidentiality and Data Protection

The increased use of information technology in the field of health care and medical practice already poses a risk of abuse and misuse of personal and medical data and of breaches of confidentiality. (For example, there is much disquiet at present in the UK concerning the NHS's Electronic Patient Record).

As with other areas of health care and medical practice, patients must be able to give an informed consent to the use of ICT implants for personal and medical data.

Patients must know who can access the data and for what purposes. Given the nature of modern health care and medical practice, medical information and data are already disclosed on what is, arguably, more than a 'need to know basis'. It cannot be assumed that when the patient gives an express consent for their data to be accessed by certain persons and for certain purposes that this express consent carries with it an implied consent for the data to be used by other persons or for other purposes which may be associated with the patient's care and treatment.

Patients must also know of their own rights of access to the data. Will patient access have to be limited in some way? Under current laws, patients may be denied access to medical data in certain circumstances. Will this be permissible when using ICT implants?

There is also a risk here of personal and medical data being used as a means of social control, particularly in cases of dangerous patients and public health matters.

Risk assessment of the potential threat to individual privacy and medical confidentiality must be undertaken. There may need to be improved data protection principles and data protection laws if ICT implants are to be used as sources of and receivers for patient information and medical records/data.

“Are Brain Implants a Threat to Our Civilisation?”*

Impressions on the “Ethical Aspects of ICT Implants in the Human Body”
Roundtable organised by the European Group on Ethics in Science
and New Technologies (EGE).

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I was invited to attend, as a representative of COMECE, a Roundtable organised by the EGE, which is an advisory body of the European Commission on ethical issues of science and new technologies. Implants of Information and Communication Technology (ICT) in the human body, in particular in the brain, are emerging at the top of areas in which fundamental ethical questions are arising. New ways of influencing the human brain are likely to emerge in the next decades, with serious implications for healthcare and society.

Prospects

The advances in psychopharmacology, neuro-imaging, brain surgery, nano-technology, informatics, agent-technology and genetics are immense. They will be developed to correct neural defects and make normal people ‘better than well’. These advances could lead to growing stem cells in patients suffering from dementia or Parkinson’s disease, but it will signify much more.

Already, high school children are swallowing Ritalin to get an edge when taking intelligence tests. It is also very likely that advances in the ability to ‘read’ the brain will be used to reveal brain states. As I write, lawyers are attempting to submit brain scans as evidence of their clients’ innocence! The problem will become even bigger when more people will want to use remote controlled electrodes and TMS (transcranial magnetic stimulation) to improve mood, increase concentration, and deepen experiences. Ultimately they will want to enhance their brains in general.

Ethical Concerns

All of these prospects are frightening indeed. Neuro-technologies have raced ahead of the ethical issues they raise. Along with all of this comes the nightmare of a ‘perfect surveillance-society.’ Ultimately, the most challenging problem of all lurks in the shadow: *modulating cognition might change our understanding of what it means to be human.*

The EGE Roundtable was meant to formulate the beginning of a discussion about the legal and institutional answers to these complex and looming problems. Four speakers were invited to express their opinions on the ethical problems that are raised by ICT-implants in the brain: a

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surgeon, an ethicist, a representative of a patient group, and a physician with a speciality in researching ICT-implants.

Many Questions: Limited Answers

The general discussion concentrated on four issues. The first raised questions in connection to what I call 'technical' aspects. Secondly a few questions were addressed about a general uneasiness in the face of the reality of brain implants, for example in relation to security. (What about involvement of the military via 'dual use'?) Thirdly, some respondents managed to converge their fears on the specific topic of the surveillance society. Finally, most other questions concerned 'classic' ethical concerns relating to the autonomy of the individual. Should patients' autonomy be guaranteed, now and forever? And in the case of remote-control: who is in charge?

In the present all pervading neo-liberalism, it comes as no surprise that the autonomy of the individual was hotly debated. Generally, in such cases one does not mean 'vertical autonomy', i.e.: the question of our relation to God. This problem, of course, was solved long ago. In today's secular societies, what people mean is 'horizontal autonomy' - the autonomy of the individual in relation to his doctor (or any other authority). Of course total autonomy does not exist. Society will always have the right – if necessary – to limit the claims of the individual. However, concerning these limits, the speakers and respondents of the Roundtable were strikingly mute.

In any case, the general discussion made one thing very clear: the questions far outnumber the answers. This being so, the most pressing need is to identify *key ethical issues*. The Roundtable unfortunately did not address the last subject.

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