

27 YEARS OF CLINICAL EXPERIENCE WITH IMPLANTABLE NEUROPROSTHESES FOR VARIOUS APPLICATIONS

Ross Davis

Neural Engineering Clinic, 76 Eastern Av., Maine, USA.

SUMMARY

Since 1973, Dr. Davis has been implanting neural stimulators and later drug pumps to restore or improve motor function in spinal cord and brain injury, stroke and multiple sclerosis. Also these neural implants have been used to modulate and decrease pain (chronic pain syndromes), spasticity (cerebral palsy, spinal cord injury, stroke and multiple sclerosis) and reduce chronic intractable seizures.

During these 27 years, many worthwhile developments in the implantable neural equipment have been realized, as well as many lessons learnt to improve operative techniques to ensure safer and improved results for the Patients.

With the advent of regulatory Boards and increasing restrictions by Health Insurance Companies, more challenges have arisen to allow new equipment and applications to be started, tested and accepted for clinical use and hopefully for payment.

The relationships between Manufacturers and 'Concept Originators' have varied over the years. Often, personalities can make or break the developmental process. The increasing needs to patent ideas/intellectual properties, which sometimes have been around for years and even previously published (missed by the patent officer), have led to vigorous legal battles, consuming money with time delays, or resulting in surrendering worth-while projects. There is a need for a responsible independent Appeals Board, made up of senior experienced Researchers, to review these disputed patent claims. Then their findings should be admissible in Court, if the case should reach this stage.

Much has been accomplished in the Neuroprosthesis area by the expanding presence of Biomedical Engineers, more scientifically trained Physician and Therapists, and successful Biomedical Manufacturers. Because of the previous and continuing investments by Private Individuals, Universities, Research Foundations, Private and Government Granting Bodies, the future for Neuroprosthetic device development and use continues to look very bright.

STATE OF THE ART UP TO 1973.

Chronically implantable neural stimulators evolved from cardiac pacemaker technology, and began in 1963 with the activation of the phrenic nerve for long-term artificial respiration. The larger field of pain control started in 1965, with a single channel stimulator activating a peripheral nerve, and in 1967 with spinal cord stimulators. In 1972 chronic cerebellar stimulation (CCS) was used to activate the human anterior lobe cortex in patients with disorders of posture and movements secondary to vascular stroke and to cerebral palsy (CP), and achieved a reduction in muscular hypertonus, so allowing functional improvements. In 1973, chronic deep brain stimulation for pain control was started.

CLINICAL EXPERIENCE WITH IMPLANTABLE NEUROPROSTHESES

In 1973, Dr. Davis started implanting stimulators chronically on peripheral nerve (PNS), spinal cord (SCS) and cerebellar cortex (CCS). PNS and SCS were used to modulate and decrease pain (chronic pain syndromes), and spasticity (spinal cord injury: SCI; stroke and multiple sclerosis: MS). CCS was used to reduce spasticity in CP and brain injury, and chronic intractable seizures.

During these last 27 years, many physicians and biomedical engineers have contributed worthwhile developments in the field of implantable neural prostheses. Many lessons were learnt to improve operative techniques to ensure safer and improved results for the Patients, and to improve the equipment the implanted.

A. Surgical lessons: The most important problem with implanting neural prosthetic devices is the appearance of an infection in the tissues surrounding the implant. After a needle specimen of the fluid around the device has been taken and cultured, antibiotics must be started immediately. Then in the next 1-3 days, the device and electrodes must be removed; and reimplanted in 6-8 weeks. The question always is how did this infection occur and how could it be prevented. Most infections occurring in the tissues around implanted devices are from the skin organisms, principally *Staphylococcus epidermitus*, which is low on the pathogenic scale and takes months to show its presence as a swelling and slight color change around the implanted and leads. Rarely, *Staphylococcus aureus* is found in the tissues around the device and usually appears in the tissues as a swelling with considerable redness usually in the first 2-4 weeks following implantation. Very rarely does a blood-borne infection occurs in the tissues around at the implant; these can occur from infected teeth, septicemia or other distant sources, especially in diabetic patients.

Preventative techniques should be followed: 1. Do a thorough skin preparation with a penetrating antiseptic solution. 2. Careful draping of the surgical area particularly with a clear plastic adhesive covering to prevent touching of the skin. 3. Irrigate all wounds with antibiotic solution regularly; leave antibiotic solution around the device and electrodes, and all wounds. 4. When closing the wounds, make sure there is no blood oozing from the tissues, and that the subcutaneous tissues are sutured tightly as a barrier, before closing the skin. 5. Skin sutures should be inserted carefully so that the edges come together evenly; this is the only barrier to stop infection. Leave the skin sutures in for 14 days as a precaution against possible skin opening. 6. Start I.V. antibiotics prior to anesthesia; continue for 10 days by mouth. 7. For future prevention of blood-borne infection: give oral antibiotics when dental surgery is undertaken, and when there are other sites of infection, particularly in diabetic patients.

B. The surgeon and implant devices: 1. It is assumed by the surgeon in the operating room that the device has been fully tested before removing it from its sterile package. 2. The Manufacturing company's "Field Engineer" should be present during the surgery to assist with any testing or calibration that has to be done to insure that the device does work. 3. The engineer should return to the surgeon's office to instruct the nurse/ therapists / surgeon as well as the patient as to how the external controller works and how the engineer can be contacted for future follow-up. Although the above appears obvious, it must also be understood that at this time only a few surgeons are interested or even skilled with the implantable devices. They are generally busy with little time to be dealing with these adjustments. In larger clinics, nurse clinicians and therapists are trained to make adjustments to the patient external controller and accessories. Only in the past 4 years has mutual interests

developed between the physicians and biomedical engineers, resulting in a sharing of each other's society meetings and journal ('Neuromodulation').

C. The relationship between the physician and the manufacturer: Following the experience of a physician implanting devices over time, new concepts of how the equipment could be improved are discussed with the manufacturer. Depending upon the manufacturer, the physician will find a combination of different responses, from one of indifference to one of a partnership, which can benefit both and eventually the patients. The physician, who is the advocate of the patient, may find a conflict of interest and then must seek legal assistance. The physician, usually intent upon publishing his results and concepts, now faces secrecy, patent applications and future royalties. The physician's time and effort now has to be redirected in order that the device development and its animal and clinical testing are carried out with the approval of the medical center's institutional review board. U.S.FDA/ CE approval for early clinical investigations must be sort and carried out prior to further approval to market the device. With a new device comes new surgical procedures; therefore applications must be made for new codings so that the insurance companies will pay for the devices and the procedures, this last step may take up to two years. The above entire process requires considerable time, collaborative effort and understanding by all parties, plus the infusion of sufficient money.

D. Patents: From most physicians' experiences, little is known of patents, the process of drafting and obtaining a patent, and the protections and problems that arise from patents in industry. Many physicians, who have examined patents related to their specialty are often surprised by a claim, for example, made in 1996, which was known by the physician to be published in the medical literature some years before. From a physician's point of view, there appears to be a basic lack of knowledge of the medical literature either by the person who is making the claim or the patent examiner. Since industry is dedicated to producing safe and useful products for the benefit of patients at considerable cost and time, it is recommended that an independent advisory board be made up of experienced medical scientists to examine and determine whether the claim is original or not, and so notified the patent examiners and, if necessary, the court.

E. Patients: Above all, the patient and the medical problem are at the center of our interest and endeavors. The devices that are conjointly developed, manufactured and tested should be of the highest quality with the best support given for its continued care and performance after implantation.

CONCLUSION

Much has been accomplished in the Neuroprosthesis area by the expanding presence of Biomedical Engineers, more scientifically trained Physician and Therapists, and successful Biomedical Manufacturers. Because of the previous and continuing investments by Manufacturers, Private Individuals, Universities, Research Foundations, Private and Government Granting Bodies, the future for Neuroprosthetic implantable device development and use continues to look very bright.

AUTHOR'S ADDRESS

Ross Davis M.D.
Neural Engineering Clinic
76 Eastern Av.
Augusta, ME, 04330
USA
email: rosdavis@qsilver.net