ELSEVIER

Medical Engineering & Physics 23 (2001) 53–60

Medical Engineering & Physics

www.elsevier.com/locate/medengphy

Basic design and construction of the Vienna FES implants: existing solutions and prospects for new generations of implants

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Received 10 November 2000; received in revised form 2 February 2001; accepted 8 February 2001

Abstract

We can distinguish 3 generations of FES implants for activation of neural structures: 1. RF-powered implants with antenna displacement dependent stimulation amplitude; 2. RF-powered implants with stabilised stimulation amplitude; and 3. battery powered implants. In Vienna an 8-channel version of the second generation type has been applied clinically to mobilisation of paraplegics and phrenic pacing. A 20-channel implant of the second generation type for mobilisation of paraplegics and an 8-channel implant of the third generation type for cardiac assist have been tested in animal studies. A device of completely new design for direct stimulation of denervated muscles is being tested in animal studies.

There is a limited choice of technologically suitable biocompatible and bioresistant materials for implants. The physical design has to be anatomically shaped without corners or edges. Electrical conductors carrying direct current (D.C.) have to be placed inside a hermetic metal case. The established sealing materials, silicone rubber and epoxy resin, do not provide hermeticity and should only embed DC-free components. For electrical connections outside the hermetic metal case welding is preferable to soldering; conductive adhesives should be avoided. It is advisable to use a hydrophobic oxide ceramic core for telemetry antenna coils embedded in sealing polymer. Cleaning of all components before sealing in resin is of the utmost importance as well as avoidance of rapid temperature changes during the curing process.

Keywords: FES; Implants; Biomaterials; Technology; Phrenic pacing; Mobilisation; Cardiac assist

1. Introduction

In general we can distinguish 3 generations of FES implants that have gained clinical relevance. Early implantable stimulators containing a very simple electronic circuit were powered and controlled via an inductive link without stabilisation measures to keep output parameters unaffected by displacement of the receiver with respect to the transmitter antenna. This construction is still in use and is acceptable if mechanical stability of the transmitter and receiver can be guaranteed, as is the case for cochlear implants [1] or in the most successful pelvic floor system, the Brindley anterior root stimulator [2]. For other applications, substantial progress awaited the second generation of FES implants, still supplied and controlled inductively but featuring stabilised output parameters. The third generation consists of battery-powered FES implants, that have gained importance in the field of cardiac pacing, are relevant to single-channel applications for dynamic myoplasty, such as cardiomyoplasty [3,4] and graciloplasty [5] and for treatment of pain, spasticity and Parkinson's disease. But for complex applications that require multiple channels and real-time control these implants are still in an early stage of development and far from clinical application. The main unsolved problem is still to achieve an acceptable battery lifetime.

The Vienna contribution to clinical FES implants is an 8-channel implantable stimulator, powered and controlled via an extra-corporal unit and an inductive link. It was applied clinically to stimulation of lower

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1350-4533/01/$20.00
PII: S1350-4533(01)00014-5

extremities of paraplegic patients and for phrenic nerve pacing in tetraplegic patients. Although it was implanted for the first time as early as 1982 its features still represent the state-of-the-art in clinical multi-channel implants for paralysed upper or lower extremities or respiratory support. During the years of application a number of modifications have led to improvements in the reliability and lifetime of the implant. An attempt to commercialise it failed after a few years because of high manufacturing costs and changes in legislation for medical products that made it impossible to maintain it on the market any longer. A number of these implants are still functioning satisfactorily in a group of tetraplegic patients who benefit from their use for electrophrenic respiration [6].

From this 8-channel implant 3 branches of further research originated with the following goals:

1. To develop a cheaper inductively-powered implant providing a higher number of output channels to support complex movement patterns of the lower extremity.
2. To develop a family of fully implantable battery-powered 8-channel implants for various applications based on a modular hard- and software concept.
3. To develop an inductively-powered implantable stimulator for direct stimulation of denervated muscles, an application that differs completely from known concepts all of which are restricted to stimulation of neural structures and indirect muscle activation.

The technology and application of FES implants have remained a major focus of research at the Vienna Department of Biomedical Engineering and Physics. Its growing importance is reflected in the foundation of a research group "FES implants", that is currently directed by Hermann Lanmüller and is intended to coordinate the activities in this research field. At the moment the limited research and development capacities are focused on an ECG-controlled version of the battery-powered 8-channel implant and its application to biological cardiac support in a preclinical stage of animal experiments [7,8].

2. Principles of construction

Inside the human body we have to deal with a highly corrosive chemically and electrochemically aggressive electrolytic medium and mechanically stressful conditions. Conversely the organism reacts sensitively to incorporated foreign bodies and corrosion products. The choice of materials that are both biocompatible and bioresistant is limited and is further reduced by technological limitations. In addition the mechanical properties needed to resist mechanical stress on the one hand and to avoid tissue damage on the other play an important part in the design of all kinds of implant.

For the construction of an FES-implant some important rules have to be considered:

1. All surfaces have to be of proven biomaterials that do not cause excessive tissue reactions even in the presence of slight inflammation of the adjacent tissue. The surfaces must not deliver material to the tissue interface or react chemically with resulting corrosion products. These attributes are provided by certain plastic materials, metals and ceramic materials.
2. The mechanical design of the implant has to be kept small in size and weight. Its surface has to be shaped as far as possible to the assigned anatomical site and it must not present corners and edges that could cause pressure damage of the adjacent tissue.
3. All electrical conductors carrying direct current (DC) have to be sealed hermetically; consequently all electrical conductors that are exposed to moisture have to be kept DC-free. This requirement applies especially to the electrode outputs and the electrodes themselves, which directly interface with an electrolytic medium and are in danger of being destroyed rapidly by electrochemical corrosion if loaded with DC [9].
4. Antenna coils for transmission of energy and/or for data transmission have to be positioned inside a hermetic capsule or if that is not possible constructed in a manner that avoids both leakage current and change of electrical capacity between different windings of the coil. The coil is usually part of a resonant circuit that is susceptible to detuning or loss of efficiency.
5. Special care has to be taken when connecting metal parts. They must not differ excessively in electrochemical contact voltage. Electrochemically equivalent materials are to be preferred, alloys should be avoided if possible and welding techniques are preferable to soldering techniques. For soldering, acid-free flux and careful removal of residues are required. Conductive adhesive is not recommended if it is to be exposed to moisture.
6. Plastic materials, including the usual medical grade silicone and epoxy polymers, do not provide hermeticity. DC-loaded parts of the electric circuit have to be enclosed in a metal or ceramic case as mentioned in 3. Metals that can be used to enclose implant electronics are made of the reactive metals titanium, tantalum or niobium with glass-to-metal-seals made from sodium-free borosilicate glass. Stainless steel is not suitable, because the alloy is decomposed during the welding process that seals the case. For data transmission with a limited data rate it is possible to position the antenna coil inside a metal case. The carrier frequency is a compromise between the shielding factor of the case and the required data rate; realistically