THE PRESENT STATE OF THE LJUBLJANA IMPLANT

[1]P. Strojnik, [2]F. Gračanin, [3]E. Vavken

[1]Faculty for Electrical Engineering, University of Ljubljana, [2]Institute SRS for Rehabilitation of Disabled, Ljubljana, [3]Surgery Department, University Hospital, Ljubljana.

Abstract

The Ljubljana implant was introduced first in 1969 in Dubrovnik. Since that time twentyone stimulators of that kind have been applied to sixteen patients. In seven years some of the stimulators failed and were replaced by new ones, some others kept on working without problems.

In this paper the Ljubljana implant is compared to the Medtronic and the Polish stimulator in some aspects. An attempt is made to determine the present state of the Ljubljana implant in two ways: The first one is to determine how many of the implanted stimulators are still in the working condition and the second one is to find out what is the reason for the failure of the broken ones.

Introduction

Nowadays, three types of implantable stimulators for the stimulation of extremities are known. The first one is produced by Medtronic, USA, and has been evaluated at Rancho Los Amigos Hospital, California /1,2/. The second one has been developed on the Faculty for Electrical Engineering in Ljubljana and is known as the Ljubljana stimulator /3,4/. The third stimulator of the kind is produced and applied in Poland and is generally referred to as the Polish stimulator. The Medtronic and the Ljubljana stimulator are intended for the stimulation of the peroneal nerve during the swing phase of the gait while the Polish implant serves primarily for the stimulation of the hand muscles /5/.

All three types of implantable stimulators have one property in common-passiveness. They obtain the energy for stimulation in the form of RF energy packages which have the parameters of stimulation pulses (frequency and pulse width). However, the implants differ in their shape and way of application. The Medtronic and the Polish stimulator have the shape of a disc and the stimulation electrodes are connected to the receiving coil by means of silicone rubber covered wires. The Ljubljana implant has the shape of a cylinder and the electrodes are its integral part. The former implants have the receiving coil wound on the rim of the disc, while the Ljubljana implant's

receiving coil is wound along the cylinder. The electrodes are made in shape of two rings at both ends of the implant. The stimulator is surgically implanted along the nerve to be stimulated or close to motor plate when muscle stimulation is in question /6/. The absence of connecting wires is the great advantage over the other two stimulators. In moving body tissues, wires are subject to mechanical and chemical stresses, which can lead to their break or to the damage of muscles or even nerves. On the other hand, positioning of the implant on the stimulation site often requires small implant dimensions. Since the components of the implant have certain dimensions, the miniaturisation is obtained on behalf of the thickness of the protective epoxide coating.

Because of the relative thinness of the protective epoxide layer, the most common failure of the Ljubljana implant is due to the penetration of body liquids into the stimulator. In our analysis we are trying to find out the present state of the Ljubljana implant, seven years after its first application to a hemiplegic pacient.

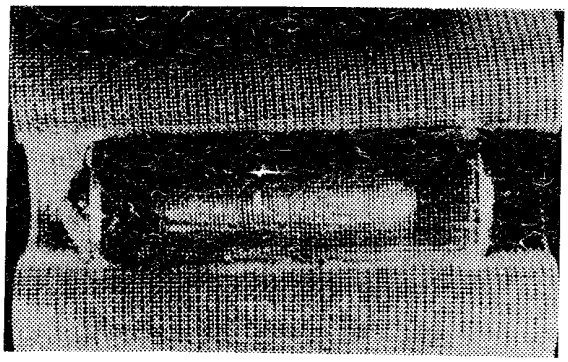

Fig. 1. The Ljubljana implant

Evaluation of the implanted stimulators

The Ljubljana implant was designed with the intention to substitute and improve the surface stimulation of the peroneal nerve with hemiplegic patients /7/. The first implant was applied to a patient in March, 1970. Altogether, the Ljubljana implant has been applied to sixteen patients. Fourteen applications were carried out within the Ljubljana Rehabilitation Centre (REC) and two within Department of Rehabilitation Medicine, (EFTO), Central Hospital, Jönköping, Sweden. In fifteen cases it was applied to benefit hemiplegic patients and in one case to improve the gait of a M S patient.

The analysis from 1975 /8/ shows that by that time five implants had failed; all of them had been removed and replaced by new ones. The shortest time to failure was eight months while some implants kept on working for

over sixty months.

Such a difference in stimulators' quality is rather unusual. To get a complete picture about the working state of all so far applied stimulators we decided to determine the parameters of the stimulators in patients' bodies. We were trying to find the dependency of ankle torque on the carrier frequency, stimulation frequency and pulse width. The dependency on carrier frequency was the most significant since it was our assumption that the body liquids penetrate into the implant and either flatten the Q curve of the receiving coil or even shift the resonant frequency. We found later that the Q curve is flattened in some cases while the resonant frequency never changes significantly.

The measurements were carried out by means of a measuring brace connected to a measuring strain-gauge bridge and an instrument according to fig. 2. The implant was fed through an antenna, connected to a pulse-modulated RF power oscillator with the output power of five watts. (ordinary peroneal brace antenna's power is no higher than 1, 5 watt). During the experiment a patient was sitting in an armchair, his affected leg being fastened into the measuring brace.

The complete measurements were carried out in nine patients and qualitative control only was made in two patients. The remaining five patients had either died or were physicaly unfit to be transported to where the measurements took place. The results of the measurements are given on Table 1.

no.	date of implant.	date of 1st reimpl.	date of 2nd reimpl.	date of control	results
1.	3.70			7.77 (88)	-
2.	4.70				
3.	11.70	11.72 (24)			
4.	12.70			7.77 (79)	+
5.	6.71				
6.	7.71	6.72 (12)		7.77 (61)	+
7.	7.71	2.72 (8)	7.73 (17)	7.77 (48)	+
8.	10.71			7.77 (69)	-
9.	11.71	5.74 (42)		7.77 (38)	+
10.	12.71				
11.	3.73			7.77 (52)	+
12.	3.73			7.77 (52)	+
13.	3.74			7.77 (40)	-
14.	3.74				
15.	1.77			11.77 (10)	+
16.	2.77			11.77 (9)	+

Table 1:

Only the month and the year are given for the dates. Numbers in brackets represent the time passed from the last implantation (in months). Denotations + and - represent the result of the control measurement. Minus means that the implant failed.

It can be seen from these results that the implant that has been working for the longest period was implanted six and a half years before. Also, all implants that were implanted in the last 38 months are still in order. From the total of 21 implants, eight have failed, which represents 38%; six implants (28%) have failed in less than fourty months.

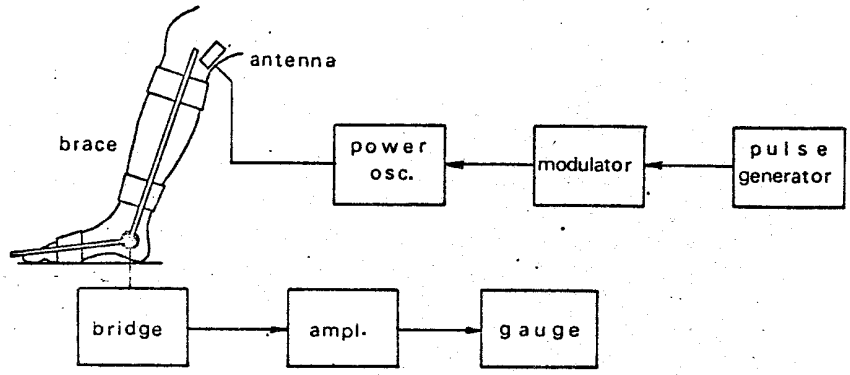

Fig. 2. Block diagram of the measurement set-up

Technological evaluation of Ljubljana implant

The measurements on implanted stimulators can only determine the number of the failed stimulators and predict, by means of the flattness of the Q curve, the failure of others in some cases. To find out exactly what happened to stimulators, we decided to examine implants removed from the body by dismantling them and thus find the reason for their failure.

There were seven implants to our disposition: five of them have been implanted and taken out of the human body while two of them were test implants, which have been immersed in saline solution for about 48 months. Every component of the implant was examined to find the source of its failure. The transaction of the implant with the denotation of single components is given in Fig. 3.

There were two types of abnormalities that we observed during our examination:

1). those due to inadequate manufacturing and
2) those caused by the influence of body liquids.

Into the first group we can place:

a) air bubbles in the outer protective epoxide layer
b) poor adherence between silicone rubber covered Dacron mesh and outer epoxide layer

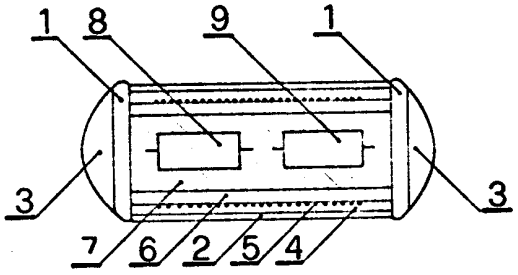

Fig. 3. The transaction of the implant: 1- Pt electrodes, 2- Silicone rubber coverd Dacron mesh, 3- silicone rubber caps, 4- epoxy resin protective layer, 5- receiving coil, 6- ferrite core tube, 7- epoxy resin core, 8- capacitor, 9- diode.

c) poor adherence between outer epoxide layer and ferrite core tube
d) air bubbles in the inner epoxide core

Into the second group we can place:

a) penetration of body liquids perpendicularly to the axis of the cylinder which has been manifested in shorting of the single turns of the receiving coil
b) penetration of body liquids along the axis of the cylinder (mostly along electrode wire), which caused the swelling of the epoxide resin in the core and as a consequence the breaking of the ferrite tube.

Examples of both kind of damage can be seen on figs. 4a and 4b respetively.

Fig. 4a Fig. 4b

Damage due to penetration of body liquids into the implants.

When comparing the original length of the epoxyde core with that of a swollen one, we found that the length increased for nearly 5% of the original length. That corresponds to theoretical expansions of epoxy resins immersed in water for longer period of time /9/.

We also measured the amount of water which was absorbed in implants. The results were obtained from two test implants and an implanted one. The amount of the absorbed water varied from 0.4% to 0.8% of the original implant weight.

Conclusion

We found out that all the stimulators, which have been in human body for three years or less still function. Not long ago, this period seemed quite satisfactory for a cardiac pacemaker to operate properly. It is true, that pacemaker is more vital for a patient than peroneal stimulator, but on the other hand, the surgical procedure is much less complicated for a peroneal implant than for a pacemaker. Nevertheless, we do feel, that the lifetime of peroneal stimulator should be increased. The results of our research show that the penetration of body liquids has been the main reason for the failure of the implants. If we could successfully fight the liquid penetration, the implant's life time would be prolonged. This could be achieved by the following:

1) thicker epoxy resin protective layer
2) omission of brittle ferrite core
3) more careful manufecturing of implants
4) use of better protective coatings than epoxy resin
5) application of new technology

Though the results with the Ljubljana implant are far from perfect, they still are promissing. The implanted system without question represents an improvement when compared to surface stimulation. The field of functional electrical stimulation has already passed the times of single channel stimulation. The need of multichannel stimulation is increasing and it is almost impossible to think of the stimulation of deeper muscle groups without the use of multichannel implantable stimulators. The experience with the simple single channel Ljubljana implant is a firm base for the further investigation and development and construction of multichannel implantable stimulators.

Acknowledgement

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