Proc. of 5th Int. Symp. on External Control of Human Extremities, ETAN, Yugoslavia, Dubrovnik 1975.

NEW SYSTEMS FOR THE CORRECTION OF URINARY INCONTINENCE USING FES

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Abstract

The analysis of well-known commercially available FES systems for the correction of urinary incontinence has revealed various deficiencies resulting from both the technical unreliability of operation and the physicians' rather poor knowledge of how these systems are functioning.

Technical laboratory investigations as well as detailed measurements of the response of the stimulus pattern to the closing muscles have provided a basis for the construction of quite new systems of electrical stimulators for the correction of urinary incontinence. These systems are more reliable, their stimulation parameters can be adjusted to the biological mechanism, and the extent of their application is larger.

Quite new electrical stimulators for FES have been developed:

1.) A system of the electrical stimulator with adjustable stimulation parameters is intended for the stimulation of the urinary tract closing mechanisms using an anal or vaginal plug. The external unit produces biphasic stimuli whose parameters are determined and adjusted by an expert for each patient individually. The duration and amplitude of the stimulus as well as the length of pause are adjustable.

2.) An automatic vaginal integrated system for the stimulation of the urinary closing mechanisms, built into a vaginal plug. This stimulator is functioning according to completely new principles. It has the form of a cylinder with hemispherical ends. Both the electronic circuit and battery supply are located inside the plug. The system is completely automatic and is started when the stimulator is inserted into the vagina.

3.) A radiofrequency implantable system with an implant with biphasic pulses that can be controlled radiofrequently. A time-function dependency of the changes of stimulation parameters can be predetermined using a program unit supplying the external unit.

The above three systems are intended for the correction of stress incontinence, post-operative incontinence, enuresis and in many instances the correction of neurogenic incontinence, such as the one in paraplegics.

The first two systems are simple to use while the third requires implantation.

Introduction

Urinary incontinence is a deplorable dysfunction, molesting an enormous number of patients. Not only it causes nuisance because of the unpleasant odour and wetness, but represents also a serious medical problem, causing various mucuous tissue and skin infections. Patients suffering from urinary incontinence are generally subjected to psychologic troubles. There exist various pharmacological and surgical methods for treatment of incontinence, but if they fail, however, an external catheter for accumulation of urine is the only solution. In this case urethra is wet all the time, infections are frequent and medical supervision is necessary. These facts have directed physicians as well as engineers to develop other methods for correction of urinary incontinence.

Functional electrical stimulation has been successfully applied in heart pacemakers, for stimulation of extremities, for detrusor muscle stimulation and for stimulation of the closing muscles of the urinary tract as well as for other diagnostic and therapeutic purposes.

Functional electrical stimulation for examination purposes is possible by means of needle electrodes in the area of perineum. For long-term application there are two systems of stimulators:

1.) An electrical stimulator with vaginal or rectal plug with two stimulation electrodes.

2.) Radiofrequency electrical stimulator with an implant and an external unit.

There are different reports on the degree of success of the same stimulator system treating similar dysfunctions. If the results reported by Stanton in 1972 (1), as well as our own experiences, are analysed, the following can be concluded:

a. Application of electrical stimulators using vaginal plugs was successful in 49% of the 96 reported cases.

b. Application of electrical stimulators using anal plugs was successful in 52.23% of the 82 reported cases.

c. Application of radiofrequency electrical stimulators was successful in 61% of the 128 reported cases.

The cases reported (ad a., ad b, ad c.) represent a sum total of all applications regardless to the type of incontinence. In all cases the stimulation used was in form of noninterrupted train of monophasic pulses with constant parameters.

From the above it is evident that the percentage of the successful application of functional electrical stimulation in correcting of incontinence is low. Bad success of stimulation has no consequences when application of intrarectal and intravaginal plugs is in question, as the stimulator can easyly be disposed of; on the other hand, the 61% of successful cases in application of implanted stimulators are terrifying, since it means that only in every second patient the operation will serve its purpose.

A rather critical evaluation of implantations from medical as well as from patient's point of view was given by Shelley (5) in 1972. According to his report, about 380 implantations had been done in England. Shelley was primarly concerned with unsuccessful cases, taking into account clinical results as well as psychological consequences, giving an assesment of successfulness of the practice as seen subjectively by the patients and by the doctors. Because of the low percentage of successful application of the existing systems he calls for a more thorough knowledge of functioning among doctors and for education of patients who should become more acquainted with the systems.

The current research has shown the following:

1.) Optimal parameters of stimulation - amplitude, pulse duration, stimulation frequency - differ from patient to patient (2)

2.) Programmed or interrupted stimulation is in most cases more suitable for long - term application than stimulation with constant parameters

3.) Monophasic stimuli have a DC component which tends to cause electrolysis, thus in many cases making successful stimulation impossible (3). It can be therefore concluded that biphasic stimulation is more suitable than monophasic.

All the stimulators in use do not have all these properties. The analysis has given directions for the research in the future as well as for development of new systems for correction of urinary incontinence by means of functional electrical stimulation. These systems are described in the following.

<u>Electrical stimulator system with adjustable parameters for correction of urinary incontinence.</u>

It is known that the relation between the amplitude of stimuli and response (intraurethral pressure) is analogue between the stimulation treshold and the pain limit. On the other hand, the relation between the frequency of stimuli and the response is nonlinear (2). Using precise measurement methods the optimal frequency can be established, this being somewhere between 15 and 25 Hz. The reason for the decreasing response in lower frequencies lies in the fact that the effective value of the signal (RMS) is smaller, which can be deduced from the Fig.1 for biphasic pulses.

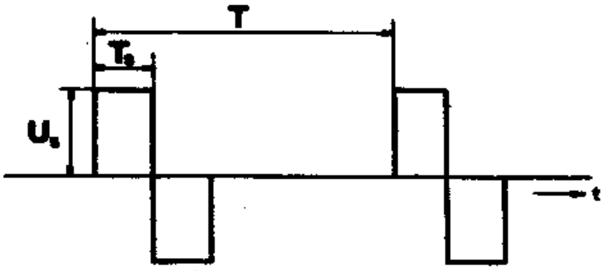


Fig.1 Biphasic stimulation

$$U_{seff} = \frac{2}{T}\sqrt{\int_0^{T_s/2} u_s^2 \, dt} = U_s\sqrt{\frac{T_s}{T}} \quad .... \quad 1.$$

$$f = 1/T \quad .... \quad 2.$$

Decrease of response when using frequencies above 25 Hz is very probably caused by habituation and reflex time of the stimulated tissue.

However, the equation 1 can be misleading. By increasing T_s and U_s the RMS value is affected and thus indirectly the response of of the stimulated musculature in lower frequencies. This is unfortunately possible only within certain limits, as the amplitude of stimuli must not be increased above the pain limit. Incresing the T_s tends to bring about (beside pain) only a temporary increase of response, primarly due to fatiguing of the striated muscles which are part of the urinary tract closing mechanism as well.

Having in mind the above conclusions two new electrical stimulator systems were developed with all the parameters adjustable, one using vaginal plug called VAGICON[R] and the other using anal plug called RECTICON[R]. Electronic circuitry is the same for both systems; it is shown on the Fig.2. The plugs are of different shape (Fig.3).

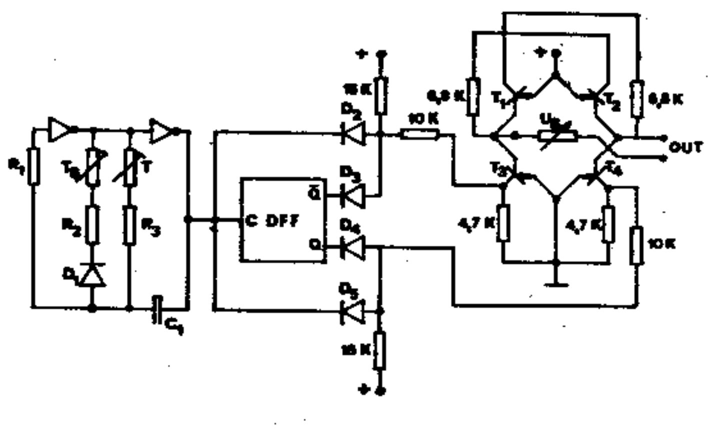


__Fig.2__ Electrical circuit of the stimulators VAGICON[R] and RECTICON[R]. Potentiometers T, T_s and U_s serve for adjusting the frequency, pulse duration and stimulation amplitude consequently.

The parameters of stimuli are adjustable within the following limits:

$$0V < U_s < 9V$$
$$0.1ms < T_s < 3ms \quad \ldots\ldots 3$$
$$40.0ms < T < 100ms$$

Fig.3 Anal plug and vaginal plug.

The adjustable parameters of the eq. 3 are set on the stimulator for each patient individually by means of the simultaneous measurement of urodynamic parameters, of whom the intraurethral pressure is the deciding factor. Fig.4 - left shows a finished stimulator, on the right is a blow-up of the electrical circuit where the three trimmer potentiometers for adjusting the parameters are visible.

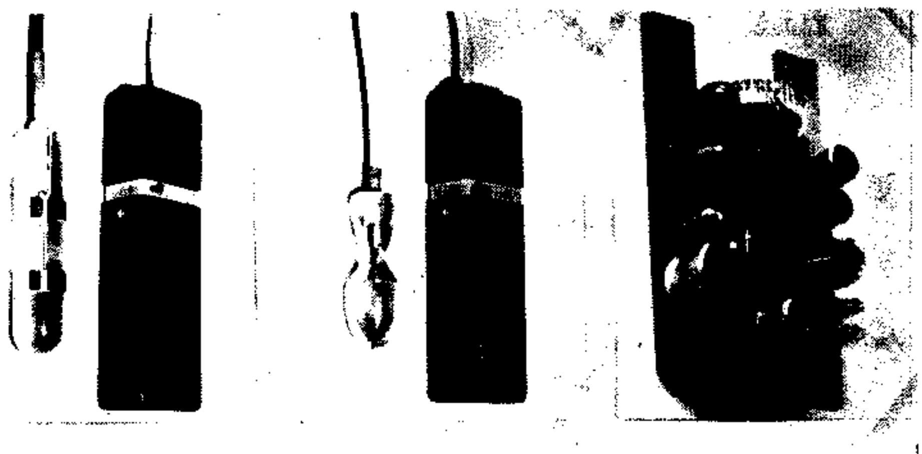


Fig.4 left: stimulators VAGICON[R] and RECTICON[R] connected to the plugs
right: the electronic circuit. U_s and T_s and T are trimmer potentiometers for adjusting the parameters.

Automatic vaginal integrated system for stimulation of the urinary closing mechanisms - VAGICON^R - X

All known stimulators must have beside the plug or electrodes an external unit containing electronic circuit and a power supply. The external unit is usually a bigger or smaller plastic box, which is cumbersome to the personal appearance especially of female patients. To avoid this unpleasant side effect, an automatic integrated intravaginal stimulator was developed. It is shown in Fig.5, and in Fig.6, disassembled.

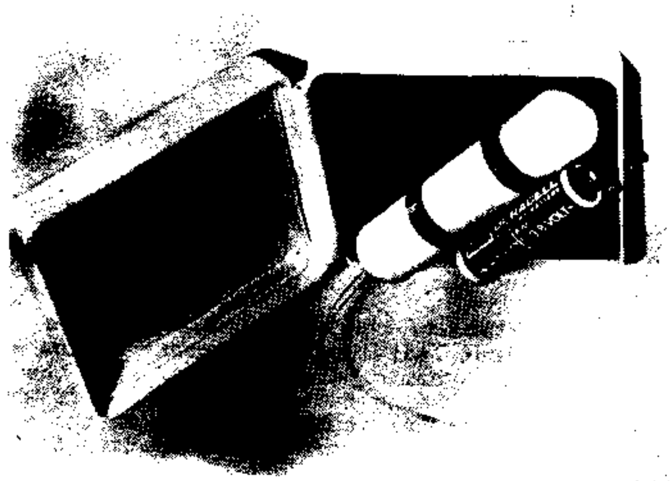


Fig.5 VAGICON^R - X

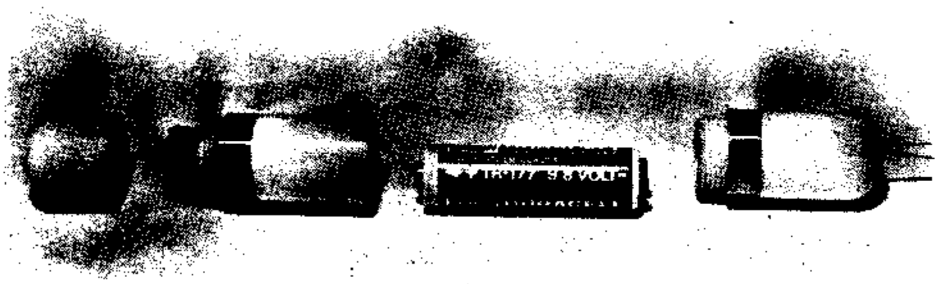
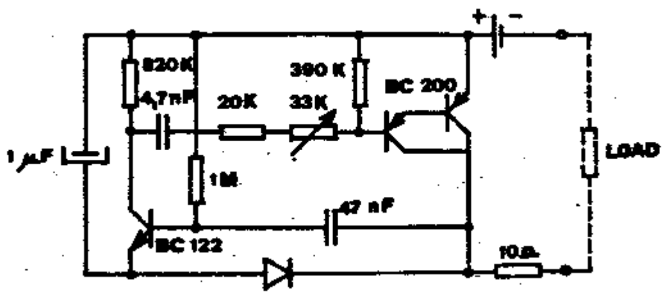


Fig.6 VAGICON^R - X, disassembled

The complete system together with battery and electronic circuit is placed in a hermetically sealed plastic housing made of teflon, while the electrodes are made of stain'less steel. The system is automatically turned on when the electrodes touch the walls of the vagina and stops, when it is taken out and cleaned with a moist piece of cloth.

The stimulator generates monophasic pulses of constant amplitude $U_s \doteq 9V$ and constant frequency f. T_s is adjustable by means of a trimmer potentiometer. The stimulation frequency can be adjusted by means of changing the resistor components of the electronic circuit shown on the Fig.7.



<u>Fig.7</u> Circuit of the stimulator VAGICON^R - X.

Parameters of every stimulator are set individually for each patient after urodynamic measurements of responses to FES.

<u>Radiofrequency implantable system using an implant generating biphasic pulses with a possibility of time-programming the stimulation pattern</u>

In the course of our work it was found out that there exist possibilities for improving the function of the existing implantable systems (Devices, Exeter). The following items were taken into account:

1. increase of efficiency
2. possibility of adjusting parameters after the predetermined time function and
3. possibility of generating biphasic pulses.

Ad 1. The first step towards improvement of radiofrequency stimulators was directed towards greater efficiency. Analysis has shown that most power losses occur in the connecting wire even though a high frequency coaxial cable is used. This disadvantage can be overcome if all the oscillator components are placed in the transmitter antenna. The other possible solution is to adapt the whole system to the coupling between the transmitter and receiver antenna, where the distance between the two should be 15mm, which corresponds to the actual conditions of application. For the convenience of the patient, batteries that can easily be obtained in the average store should be used.

Along these lines a concept for construction of the system, shown on Fig.8, was developed.

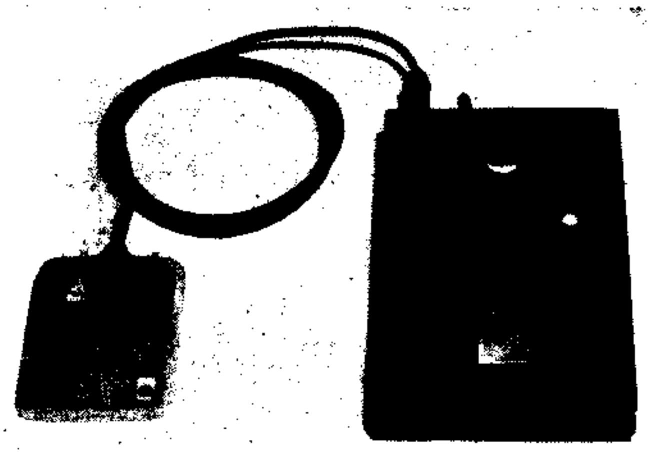


Fig.8 Laboratory-made and tested new transmitter system

On the left side of the photo the housing can be seen. It contains the biasing battery (6 AF 22 - IEC). In Yugoslavia this kind of batteries is manufactured by the factories Zmaj, Croatia and EI Niš. They are commonly used for transistor radio-receivers and can be purchased without difficulty. Inside the housing there is also an astable multivibrator - pacer, which biases the transmitter with pulses via a cable. The transmitter is placed inside the antenna frame and is coated in acrylate. The essential feature of this system is that the high-frequency energy is generated in the transmitter coil itself and is not transported through the connecting cable.

By special adjusting the optimal coupling was acchieved when the antennae were placed 15 mm apart from one another. As it is evident from the diagrams on Fig.9, the other systems are tuned in such a way that both antennae are held together. The new system PRS is tuned on the distance 15 mm, which means that 70% of energy, which represents pure losses in the other systems, is spared.

Considering these improvements, the amplitude gained at the output of 200 ohms is 20 V, having a biasing battery of 9 V and mean value of the DC current consumed 2.5 mA. For illustration: the Devices system gives at 15 mm spacing and biasing battery of 12.15 V only 7 - 8 V of stimulus with current drain of 2 mA, and the Exeter stimulator even 3 - 4 V at the output with a battery of 15 V and current drain of 3.5 ma. The values are clearly seen in Table I.

Table I   Electrical values of the existing stimulator and the new system

Receiver	Biasing voltage	Biasing current	Power drain	Amplitude of stimulus
Exeter	15	3.5	52.50	4
Devices	12.5	2	24.30	7
PRS	9	2.5	22.50	14

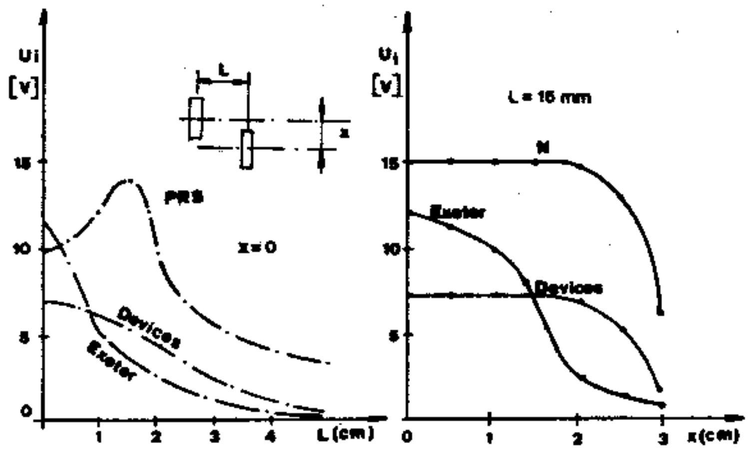


Fig.9   Height of the stimulation pulses related to the distance between the transmitter and receiver antenna.

As a conclusion we can point out that the new system PRS gives at the same power on the same load a stimulus, which is twice as strong as that of the Devices, i.e. has (because of $P=U^2/R$) a four times smaller power drain under the same output conditions. The battery life - span is therefore four times longer. We consider this an important aspect since frequent changing of batteries is obviously a rather inconvenient obligation for the patient.

Ad 2 and 3: Solution of these problems is to be searched for in the right combination transmitter - receiver. The transmitter which was developed on the principles stated above is shown on the Fig.10.

The transmitter has very convenient dynamics of all the stimulation parameters. An example of the programmed biasing is given on the Fig.11. The pulses at the output of the implant are of the same shape.

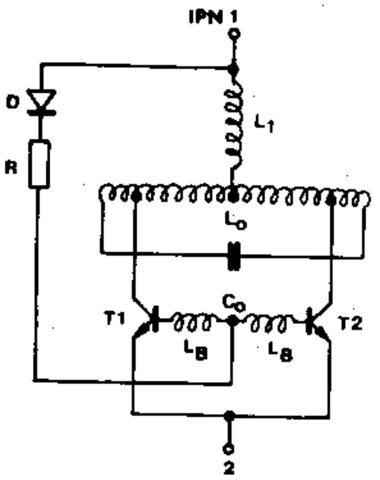


Fig.10 An example of a transmitter for programmable stimulation. The output of the programmed biasing circuit delivers the necessary energy and information at the same time.

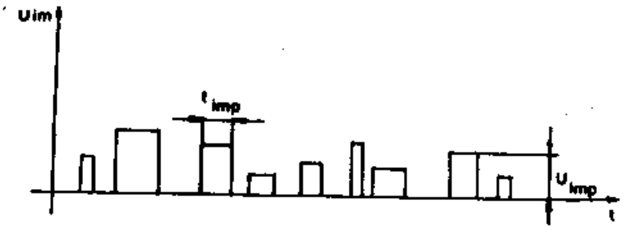


Fig.11 Programmed (stochastic) stimuli.

Parameters T_s, T and U_s at the output of the implant can thus be changed by the transmitter bias; biphasic action is made possible by the receiver itself.

The basic principle of the stimulator is that the transmitter determines the duration of the positive and the negative pulse by means of width-modulation. The amplitude of the pulses is defined with the pulses from the transmitter. Thus it is possible to adjust all the stimulation parameters externally. In the receiver there is an electronic circuit, which shifts the phase of every other pulse for 180 deg. (Fig.12).

The receiver part on Fig.12 is a resonant circuit, biasing the output bridge with pulses. The same pulses trigger the COS-MOS bistable multivibrator. Signal from the multivibrator switches on the corresponding transistors of the output bridge. The output stage is a complementary transistor array, represented in the scheme with T_2 to T_5.

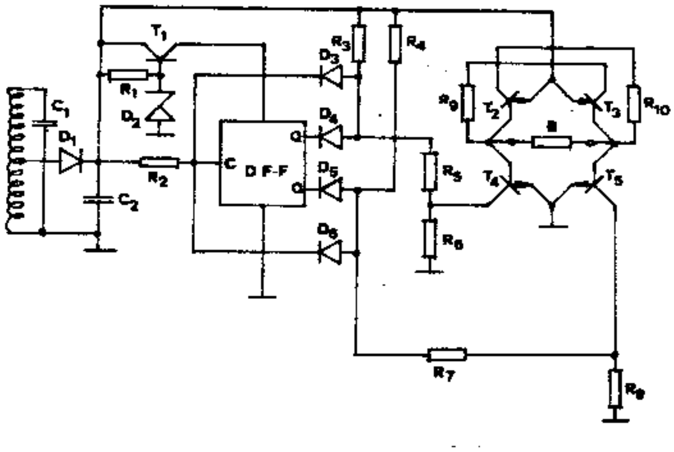


Fig.12 Electronic circuit of the receiver with externally adjustable parameters of stimulation.

In this scheme the pulse duration is defined with the duration of the 100% modulation, while the polarity of the pulses depends on the outputs of the bistable multivibrator.

The transmitter system is a classical version, suitable for interrupted or programmed stimulation.

Evaluation of the effects of FES (nonimplantable systems) on the urethral closing muscles in patients with stress incontinence

As the method for evaluation of the effects of FES served the method for measuring urethral pressure profiles by means of a sensor tip catheter (4).

In 20 female patients suffering stress incontinence the effects of the following types of stimulation were measured:
- mechanical - anal and vaginal
- electrical - biphasic and monophasic, using vaginal and anal plugs (large - D = 25 mm, medium - D = 18 mm, small - D = 2 mm).

The following parameters were considered significant:

a. Differences between the intervals of continence with and without stimulation in individual female patient.
b. Differences between the maximal intraurethral pressures with the stimulation applied and the maximal intraurethral pressure without stimulation in individual female patient.

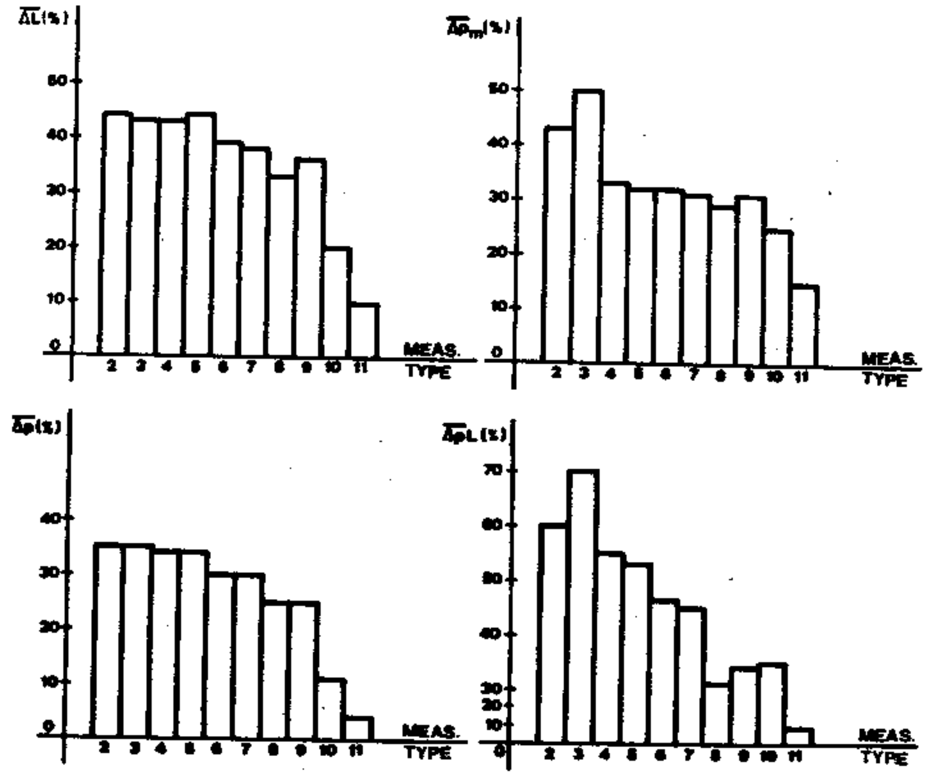


Fig.13 Histograms of the mean values of the parameters measured in 20 patients with stress incontinence by measuring urethral pressure profiles.

The values are given in percent of the mean value of the lenght of the interval of continence $\overline{L}_1$, maximal pressure $\overline{p}_m$, mean pressure $\overline{p}_1$ and integral above the intèrval of continence $\overline{pL}$ in profiles without stimulation (1 - measurement - urethral profile without stimulation).

$\Delta\overline{L}$ (in % of $\overline{L}_1$) - increase of the interval of continence
$\Delta\overline{p}_m$ (in % of $\overline{p}_m$) - increase of the maximal pressure
$\Delta\overline{p}$ (in % of $\overline{p}$) - increase of the mean pressure
$\Delta\overline{pL}$ (in % of $\overline{pL}$) - increase of the integral above the interval of continence

Types of measurements: 2 - vaginal monophasic FES, 3 - vaginal biphasic FES, 4 - anal large size plug, monophasic FES, 5 - anal - large size plug - biphasic FES, 6 - anal - middle size plug - monophasic FES, 7 - anal middle size plug - biphasic FES, 8 - anal small size plug - biphasic FES, 9 - anal - small size plug - biphasic FES, 10 - mechanical stimulation caused by the vaginal plug alone, 11 - mechanical stimulation caused by the large size anal plug alone.

c. Differences between the mean values of intraurethral pressures above the interval of continence with and without stimulation in individual female patient.
d. Differences between the integrals of the urethral pressures above the interval of continence with and without stimulation in individual female patients.

The interval of continence is defined as the lenght between the first maximum of the intraurethral pressure (in case that there are several) as seen from the outlet of the urethra to the bladder and the point where the pressure in the urethra rises above the intravesical pressure as seen from the bladder to the outlet of the urethra.

In each patient separately the optimal parameters of FES were determined. From the results of measurements (Fig.13) the following was concluded:

a. Vaginal stimulation was the most successful. A substantial increase of all the four parameters was observed. Biphasic FES evokes the best responses, monophasic stimulation follows. The effect is partly due to the effect of the vaginal plug, this mechanically compressing the urethra.
b. Anal FES with the large size plug is the second most successful. In these cases there is no significant difference between the monophasic and biphasic FES in all four parameters.
c. Anal FES, medium size plug is placed third. Also in these cases no significant difference between the monophasic and biphasic FES in all the four parameters was observed.
d. Success of the stimulation is largely depending upon the size of the anal plug. (A bigger plug makes possible a better contact between the electrodes and the sphincter tissue). The bigger the plug, the better the response to FES.
e. In general there were no substantial differences observed between the monophasic and biphasic FES, except when using vaginal plug.
f. Urethral stress profiles varied a great deal from case to case.
g. Repeatability of the measured profiles was within acceptable limits.

Conclusions

Three new electronic systems for rehabilitation of urinary incontinence were developed:

- VAGICON^R and RECTICON^R, both using the same electronic system, for application with vaginal and anal plugs. Their advantage is the possibility for adjusting parameters for the individual need of each patient.
- VAGICON^R - X, unique as regards phisical and electrical design principles. The device generates monophasic pulses and is started when inserted into the vagina.
- PRS - radiofrequency system was designed for better efficiency. It generates biphasic pulses in the implant.

As regards the electrical and mechanical construction, as well as the method of application, the nonimplantable systems are much more suitable than the implantable ones. The reason for this is that there is no interfering with the human organism; negative side effects are reduced to minimum, the device can be removed any time if complications set in or in case that the patient is cured. The above examinations are an example of a successful evaluation of the effects of FES on stress incontinence using nonimplantable systems, by application of the exact method of urethral pressure measurements by means of sensors applied directly to the measured location. In all the patients that underwent the examinations all the types of FES evoked significant increases of the intraurethral pressure (up to 50%). The final and more objective evaluation of FES therapy will be done in the second part of the examinations after long - term application of the electrical stimulators VAGICON^R, RECTICON^R and VAGICON^R - X.

The next phase of the research is directed towards evaluation of implantable systems. We expect to have success in those cases where stimulation with nonimplantable systems failed, in the first place in rehabilitation of paraplegic patients. Preliminary results show that good effects can be expected using programmed, long-term stimulation.

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