Activation of the calf muscle pump action by electro-stimulation with VeinoPlus# device.

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Summary

Purpose of the study
To study the effect of the electro-stimulation with the VeinoPlus™ device on the physio-pathology and quality of life patients suffering from distal venous stasis and also from insufficiency of saphenous veins.

Material and methods
The study carried out was of non-randomized experimental type. The inclusion criteria for patients were to have pains of venous origin and venous insufficiency classified as C0S or C1S or C2S according to classification CEAP and saphenous incompetence. A duplex Doppler Ultrasound scan was performed at the initial examination, to evaluate the VeinoPlus™ physio-pathological effects on the reflux. Then each patient filled out a QOL CIVIQ-2 questionnaire.
The patients used the VeinoPlus™ for 20 minutes daily during three weeks. During the last exam the questionnaire CIVIQ 2 was filled out.

Results
Physio-pathological effects were studied on 20 patients. The VeinoPlus™ electro-stimulation restored physiological venous flow and drained the calf muscles of the blood accumulated there. The effect of VeinoPlus™ stimulation on the quality of life was studied on 40 patients and demonstrated significant improvement of the quality of life of these patients.

Conclusion
VeinoPlus™ by the way of electro-stimulation of calf muscles is of significant interest for venous insufficiency treatment. It ensures distal venous draining and significantly improves the quality of life of patients.

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 # VeinoPlus ™ is the registered trademark of stimulators manufactured by AdRem Technology, 162 rue Fauburg St. Honoré, F-75008 Paris, France

Introduction

The purpose of this study was to measure the effects on physiopathology as well as to evaluate parameters of the quality of life after using VeinoPlus™ stimulator applied to activate the calf muscle pumping action.

It is not necessary to explain again the venous congestion effects on distal veins whose different symptoms have the same origin caused by chronic venous insufficiency and venous / lymph stasis.

Physiologically, when walking, the musculo-aponeurotic pump of calf muscles is responsible for the major part of the driving force to make the venous return toward the heart (1).

There are certain factors, which are at the origin of this muscle pump incompetence. These are: old age of patients, obesity or ankylosis of the ankle joint and also amyotrophic changes of all origins as well as all the post-traumatic and rheumatic problems of lower extremities. It also includes all clinical situations, which confine patients to immobility (the particular case of pregnant women will be treated in a later study). This is also the case for certain professions such as those performing sedentary work (computer operators, office employees…) or standing jobs (hostesses, nurses, cooks, restoration workers…). Not even to mention multiple numbers of long trips (plane, train) which modern life imposes on everybody. In total, it includes all life situations where inactivity replaces physical activity.

The interest to use electro-stimulation in order to provoke muscle contractions was reviewed by Hainaut and Duchateau (2). They stated that the muscle contraction provoked by electro-stimulation produce similar mechanical effects to voluntary exercise. In the study conducted by Man, Lepar and Cywinski (3), the electro-stimulation was used to reduce the swelling volume of legs and ankles in healthy volunteers, caused by long time standing position.

In the Department of Phlebology at the Saint-Michel Hospital in Paris, it was interesting for us to evaluate the effects of sural contractions induced by the Veinoplus electro-stimulator on patients who have muscle pump limitations and were consulted for functional symptoms of veins.

Description of the VeinoPlus™ device.

The VeinoPlus™ stimulator device delivers electrical impulses into a vicinity of motor points on the muscle via skin-patch electrodes. Depending on the quality of the delivered electric signal, the muscle contraction can be less or more comfortable (4).

The VeinoPlus™ neuromuscular electro-stimulator used for our study has a similar volume to a pocket size Walkman and was powered by one 9 volt alkaline battery.

Its function was to evoke the contraction of calf muscles by electro-stimulation in order to squeeze blood from deep veins situated in lower leg.

The goal of this compression was to eject venous blood and the lymph from legs toward the heart in the subjects of the study (the patients).

The stimulator VeinoPlus™ was applied on the legs of the patients by means of only two auto adhesive VeinoPack™ electrodes in oval shape and size by 8 x 13cm supplied by AdRem Technology. The electrodes were placed on skin at the level of the central posterior part of calf in symmetrical way one electrode on the left and one electrode on the right legs. With this type of electrodes and their placement, the stimulation current

flew through the entire leg and part of pelvis, but provoked targeted action mostly on the calves. The density of the stimulation current was in fact strongest in the region directly under the electrodes, that means on the calves.

The electrodes were in turn connected to the two ends of output cable of the VeinoPlus™ stimulator. This stimulator is certified with the CE mark as a medical device and according to the manufacturer specification it produces electrical impulses of low voltage and small energy (charge below 25 micro coulombs per impulse), which is well below the limit of safety established by the American Standard AAMI-ANSI Standard for Transcutaneous Stimulators NS4-85 and meets international standards like IEC 60601-2-10 and it is also certified in compliance with European Community CE Council Directive 93/42/EEC Annex V and Essential Requirements Annex 1.

VeinoPlus™ produces a train of impulses with rectangular voltage waveform when connected to the electrodes. During a treatment the waveform of current of every impulse is symmetrical and exponential (nonrectangular) biphasic. These impulses cause powerful and almost symmetrical calf muscle contractions on each leg.

In electrical terms, the impulses delivered by the VeinoPlus™ are of low voltage and their strength is manually selected by pushing switches in a range from 0.5Vp to 50Vp, (Vp= peak value of voltage of impulses) depending on patients' tolerance and sensitivity. The value of delivered voltage is read on the LCD screen on the device.

In order to provide a consistent pattern of stimulation, the rhythm of impulses was preprogrammed in the VeinoPlus™ chip memory. In the course of the study, neither the patients nor the medical personnel were able to change the rhythm of the impulses and the duration of each treatment, which was 20 minutes. (The stimulation stopped automatically after 20 minutes). ….

The rhythm of the impulses of the VeinoPlus™ is defined by bursts, which were painless when producing muscle contractions, and burst repetition rates were close to a cardiac rhythm.

The elapsed time between each burst changed automatically every 5 minutes during treatment. This was corresponding to one burst per second for the first 5 minutes followed by bursts every 0.8 seconds for the 5 subsequent minutes, and then by bursts every 0.7 seconds for another 5 minutes and finally by bursts every 0.6 seconds for the last 5 minutes. The intervals between bursts of stimulation corresponded to the following values of beats-per-minute: 60bpm, 75bpm, 86bpm and 100bpm respectively.

For each treatment of 20 minutes, VeinoPlus™ produces 1600 burst of stimulation resulting in at least 1500 effective contraction of muscles in each calf.

If the electro-stimulation by VeinoPlus™ device induces contractions of striated muscle that were macroscopically visible, what was happening to the smooth fibers of the venous wall? Did they restore the venous return in patients with venous incontinence? Did they diminish venous stasis in the interest of improving of life quality, relief of pain in population of patients with reduced mobility?

This is to respond to these questions that we have undertaken this preliminary study.

Preliminary study

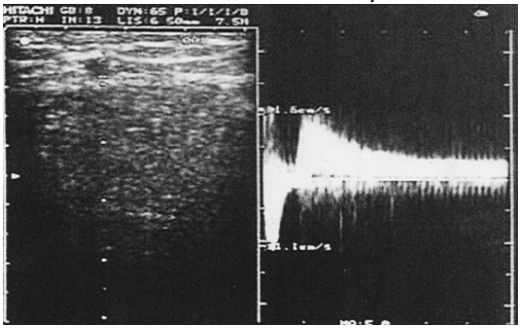
Effects of VeinoPlus™ on physiopathology of calf veins

Twenty patients under this part of study underwent preliminary echo-Doppler examinations.
Only the patients in whom in absence of sural contraction, the external saphenous vein (as recorded at popliteal fossa) was incontinent during control relaxation of muscles and demonstrated also incompetence of the posterior valves were selected for further study. The held criteria for the diagnosis of incontinence are that from the international publications, that means the time of reflux greater than 0.5 seconds.

We have measured the venous sural reflux by compression – release of sural triceps. This reflux was then measured successively during static isometric contraction under electrostimulation by VeinoPlus™ in order to evaluate hemodynamic consequences of this technique.

An isometric static contraction of the sural triceps led to the time of flux and subsequently the time of intense reflux of above 0.5 seconds during the releases shown on the **Photo 1**, below.

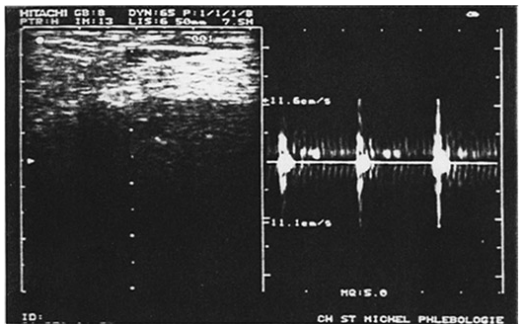
Photo 1: Incontinent small saphenae



A dynamic contraction of sural triceps by movement of flexion-extension of ankle in orthostatic condition assured a venous drainage during contraction with an identical reflux.

In patients undergoing the VeinoPlus™ electro-stimulation, each of the contractions of sural tricepses caused simultaneous ascending flux. It was recorded in twin veins and in external saphenous vein. The reflux was also always visible, but tempered by the ascending flux resulting from each calf muscle contraction. The time of reflux has become negligible (<0.5s) and has not exceeded the time of the ascending flux. Due to the rhythmof flux imposed by the electro-stimulation, the reflux was not visible. The vein appeared like 'arterialised'. Each induced muscular contraction pushed and carried the blood upward. The electro-stimulation permitted to trigger off the upward flow and significantly reduced the time of reflux as illustrated on the **Photo 2**.

Photo 2: "Arterialisation" of a vein.



When the stimulation stopped, the external saphenous vein no longer showed the spontaneous flux. When we have caused a chase of venous blood by tricipital compression and the flux and reflux have became less marked in respect to the initial state.

Conclusions

The electro-stimulation with Veinoplus™ emptied temporarily the venous blood from legs, which was accumulated there before putting on the stimulator. The electro-stimulation corresponded to a certain level of muscular activity obtained during walking. We have restored almost a physiological venous blood flow. Veinoplus™ increases the effect of compression stockings alone.

Material and methods

The study performed was of the type experimental not randomized. The objective of the study was to evaluate physiological consequences of the electrostimulation by the Veinoplus™ on contractions of venous walls, the direction of the venous flow and the quality of life of patients. The study was realized with the sample of 40 voluntary patients selected from the ambulatory group consulted by the department of phlebology of the hospital Saint-Michel in Paris.

The inclusion criteria to the protocol were: presence of the pain of venous origin due to insufficiency classified as C0S or C1S or C2S according to the CEAP classification with external saphenous incontinence confirmed by previously done Doppler ultrasound. Before the experiment, every patient filled out a quality of life questionnaire CIVIQ2. Subsequently, every patient was given the Veinoplus™ stimulator with the instruction to use it once every evening for 20 minutes during three weeks. After three weeks, the patients were reviewed and asked to fill out again the questionnaire CIVIQ2. The questionnaires were then submitted to laboratory of applied anthropology of Professor Mollard at Saints-Peres School of Medicine in Paris to review the results, perform statistical analysis and interpretations.

The method of data collection was done with purpose to evaluate the effects of treatment by Veinoplus™ via the questionnaire CIVIQ2 filled out before and after the treatments. The statistical analysis followed the measurement plan called repetitive. The parametrical variables measured corresponded to a subjective evaluation scored on the scale from 1 to 5 in response to 20 questions. These scores permitted to quantify a symptom, a sensation or a limitation: the score “1” on the scale showed the absence of symptoms or limitations while the scores in a range from 2 to 5 permitted patients to evaluate the intensity of sensation or limitation.

The questionnaires from before and after treatment were collected from 40 patients.

The analysis was split into two steps. The first step consisted of analysis of each question by calculating the average of ratings. These 20 questions were grouped into 4 categories, according to the analysis method by the questionnaire CIVIQ: namely, the feeling of the general pain, the physical repercussions, the psychological repercussions and the social repercussions. The second step consisted of application of the codification method of the questionnaire CIVIQ. This method permitted to calculate the score expressed in percentage for each of its four dimensions. The method of calculation as follows:

d= (S-m) / **(M-m) x 100** *where:*

S: represents the sum of scores corresponding to patients responses to given questions, m: represents the theoretical minimal value while all the responses are at first level of graduation of scoring for all the items related to the dimension,

M: represents the theoretical maximal score while all the items are quoted at maximum graduation level for all the items related to the dimension.

The result of 0% corresponds to the best possible quality of life, while 100% refers to the worst quality of life.

For the set of these variables, the average values were compared to the mean of statistic test namely like the test t of Student on paired series or the test non parametric of Wilcoxon.

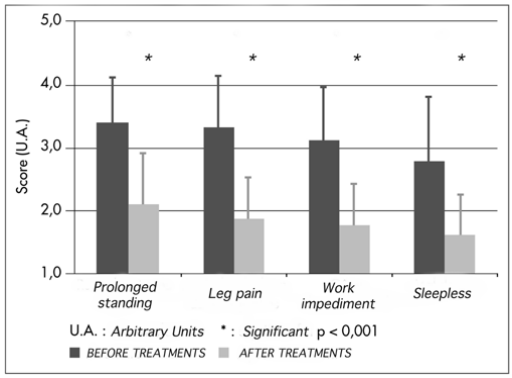
Results

1) The effects of Veinoplus on physiopathology of venous insufficiency. The effects physiopathologic of Veinoplus™ were already discussed in the chapter of preliminary study.
2) The effects of Veinoplus™ on the quality of life of patients. Forty patients (thirty eight females and two males) were included in the protocol of evaluation of the quality of life. The results were obtained from the response of 38 patients who were filled out the questionnaire correctly before and after the treatment two out of forty (number 13 and 35) did not manage to fill out the questionnaire after the treatment correctly.

The **Table 1** and the **Graphs** number 1 to 4 show the mean results obtained for each question from questionnaires filled out before and after the treatment. For each of the 4 categories, the questions are classified in order of importance, in a first place they were most important and in a last place they were less important.

Concerning the "General pain" category as illustrated on the **Graph 1**, we observed the mean values of scores before treatment being between 2.79 and 3.39 (see also the **Table 1**). The scores on pain significantly diminished after utilization of the Veinoplus™ and reached the mean values oscillating between 1.61 and 2.11. The most important reduction was observed for leg pain and the least important reduction was related to sleeplessness (**Table 2**).

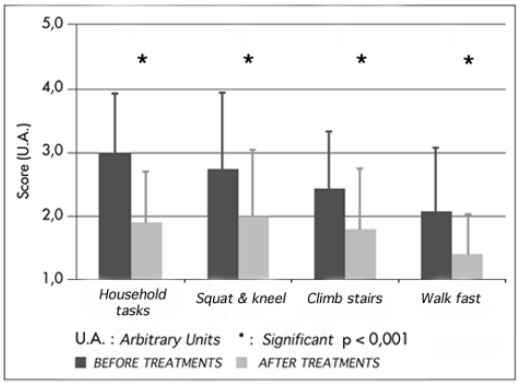
Graph 1: *General pain category*
N=38 patients



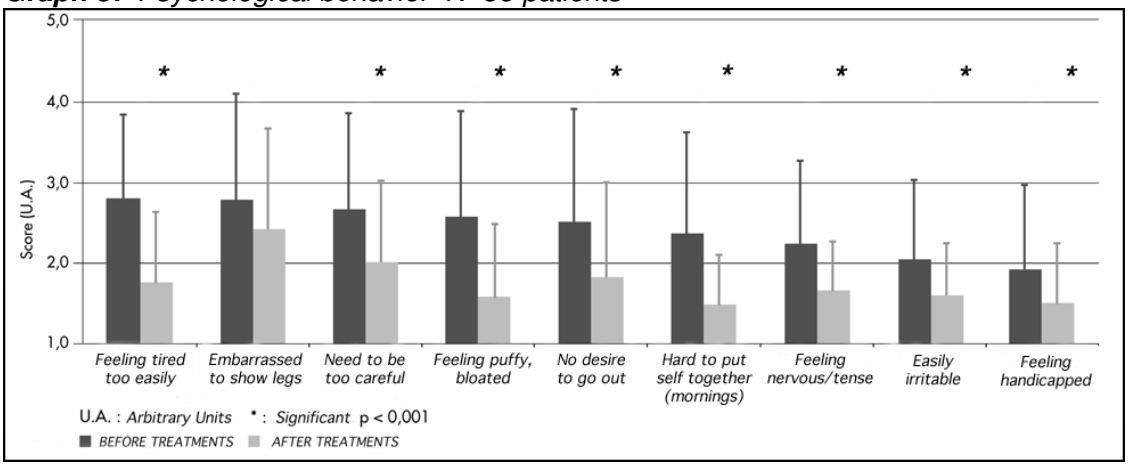
The results that deal with "physical repercussions" show the fluctuations of the same order (cf. **Graph 2**). The effect is significant whatever the physical task is, with the notable difference, however, in amplitudes of the decreases. Concerning the "performance of household tasks", the difference in order of 1.13 (cf. **Table 2**) is clearly bigger than the differences observed for "squat or kneel", "climb several flights of stairs" or "fast walk". It should be noted that the physical activities, which we can qualify as less dynamic (e.g. when performing certain household tasks) showed less good scores before treatment whereas for "fast walk", the patients felt less restricted before the treatment.

Concerning the questions referring to the category of psychological behavior of patients, the effect of Veinoplus™ is significant with no exception, however, with variations (cf. **Graph 3**). The issue of "feeling tired too easily" is without doubt the most felt factor before the treatment, and on which the treatment had the most impact (maximal reduction of 1.05).

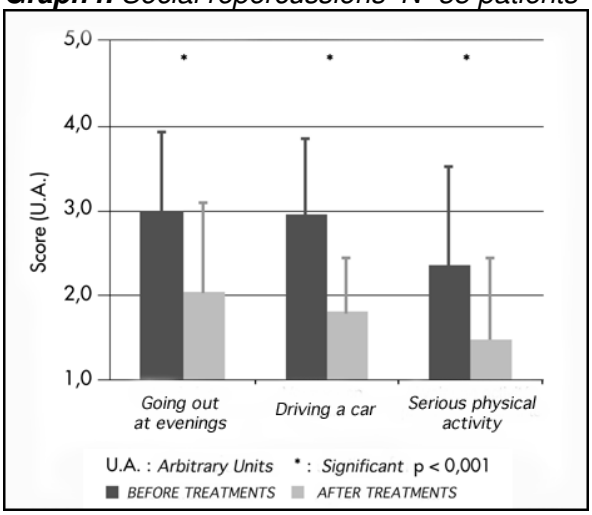
Graph 2: *Physical repercussions*
N=38 patients



Graph 3: *Psychological behavior N=38 patients*



Graph4: *Social repercussions N=38 patients*



According to the indicated differences in the **Table 2**, the Veinoplus™ had different impacts on three groups of the questions:

- Important impact for the fact of "feeling tired too easily", the "impression of being bloated, puffy",and "morning difficulties to put self together" (difference between 0.87 and 1.05);
- Medium impact on "lack of desire to go out", "need to be excessively careful " and "being nervous" (difference in order of 0.60);
- Weak impact on being: "Easily irritable" , "Feeling of being handicapped", "Embarrassed to show own legs" (differences between 0.37 and 0.47).

These results well illustrate the benefits of using Veinoplus™ on psychological well being of patients in terms of fatigue and of psychological firmness or functional readiness.

Concerning the 'social repercussions', the use of Veinoplus™ is equally significant (cf. **Graph 4**).

The **Graph 5** shows the results after the applying the method of codification of the questionnaires CIVIQ. The feeling of generalized pain is constitutes the variable which corresponds to the worst score before treatment and is equal to 53.9%. The three other categories, which qualify the repercussions of social, physical and psychological order represent the percentages below 50%. It is worth to note that the changes in the social behavior are more important than in physical and psychological behavior.

After use of Veinoplus™, the score in all 4 categories reached a percentage near 20%, which can be translated to the beneficial and significant effect of this electro-stimulation treatment.

The evaluation of the effects on the quality of life following the treatment by Veinoplus™ electro-stimulation showed a significant improvement for the totality of the questions as well as for the score expressed in percentage of the variation for each category.

Conclusion and perspectives

The electro-stimulation with Veinoplus™ can be considered as a treatment of choice to supplement therapeutic strategies targeted to diminish effects of venous stasis. By stimulating musculo-aponeurotic pump of calf, it permits to increase the sural flow and to assure emptying distal veins. The quality of life of the patients was significantly improved after 3 weeks of daily use of Veinoplus.™

The promising results were also obtained in healing of venous ulcers with the Veinoplus™ and we have already started a study aimed at this indication.

The use of Veinoplus had a non negligible contribution to correct functional problems induced by venous stasis, especially in clinical situations where graduated compression therapy is difficult to do. This is also a case:

1. During the period of heat or in the countries with hot climate,
2. In insufficiency of calf muscular pump due to obesity or ankle ankylosis,
3. In the post thrombophlebitis syndrome,
4. In the professional situation at risk,
5. In all the situations of life when the physical activity is reduced.

In total, the use of Veinoplus makes non negligible contribution to correct functional problems induced by venous stasis.

Table 1: *Mean results*

		Before treatment		After treatment	
	Question	Mean	Dev	Mean	Dev
General pain					
Prolonged standing	Q 4	3,39	0,72	2,11	0,80
Leg pains	Q 1	3,32	0,81	1,87	0,66
Impediment at work	Q 2	3,13	0,81	1,76	0,68
Sleeplessness	Q 3	2,79	1,02	1,61	0,64
Physical repercussions					
Performance of household tasks	Q 9	3,03	0,88	1,89	0.69
Squat or kneel	Q 6	2,68	1,23	2.03	1.03
Climb several flights of stairs	Q 5	2,42	1,00	1,76	0,94
Fast walking	Q 7	2.05	1,06	1,39	0,64
Psychological behavior					
Feeling tired too easily	Q 13	2,82	1,01	1,76	0,85
Embarrassed to show legs	Q 16	2,79	1,32	2,42	1,27
Need to be too careful	Q 15	2,63	1,20	2,03	1,00
Feeling puffy, bloated	Q 14	2,55	1,29	1,58	0,86
No desire to go out	Q 20	2,50	1,37	1,87	1,14
Hard to put self together (mornings)	Q 19	2,37	1,20	1,50	0,60
Feeling nervous/ tense	Q 12	2,24	1,02	1,63	0,67
Easily irritable	Q 17	2,03	1,00	1,55	0,72
Feeling handicapped	Q 18	1,89	1,09	1,47	0,86
Social repercussions					
Going out at evenings	Q 10	3,03	0,97	2.08	1.02
Driving a car	Q 8	2,92	0,91	1,76	0,68
Serious physical activity	Q 11	2,39	1,10	1,58	0,83

Table 2: *Classification in function of the effects of treatments*

	Question	Difference*	Rank
General pain			
Leg pains	Q 1	1,45	1
Impediment at work	Q 2	1,37	2
Prolonged standing	Q 4	1,29	3
Sleeplessness	Q 3	1,18	4
Physical repercussions			
Performance of household tasks	Q 9	1,13	1
Fast walk	Q 7	0,66	2
Squat or kneel	Q 6	0,66	3
Climb several flights of stairs	Q 5	0,66	4
Psychological behavior			
Feeling tired too easily	Q 13	1,05	1
Feeling puffy, bloated	Q 14	0,97	2
Hard to put self together (mornings)	Q 19	0,87	3
No desire to go out	Q 20	0,63	4
Need to be too careful	Q 15	0,61	5
Feeling nervous/ tense	Q 12	0,61	6
Easily irritable	Q 17	0,47	7
Feeling handicapped	Q 18	0,42	8
Embarrassed to show legs	Q 16	0,37	9
Social repercussions			
Going out at evenings	Q 8	1,16	1
Driving a car	Q 10	0,95	2
Serious physical activity	Q 11	0,82	3

* Difference = mean value before treatments less mean value after treatments

References.

[1] ZUCCARELLI F, KOSKASI. : Varices et insuffisance veineuse chronique. Encycl Méd Chir. (Editions scientifiques et médicales Elsevier SAS, Paris) AKOS Encyclopédie Pratique de Médecine, 2-0500, 2003 7p.
[2] General Review Article on Electrostimulation: Hainaut K, Duchateau J, «NeuromuscularElectrical Stimulation and Voluntary Exercise» in: Sport Med 14(2)100-113, 1992.
[3] MAN, IOW, LEPARGS, MORRISSEYMC, ANDCYWINSKI JK.: Effect of Neuromuscular Electrical Stimulation on Foot/Ankle Volume during Standing. Med. Sci. Sports Exerc., Vol. 35, N°4, pp. 630-634, 2003.
[4] BISSCHOPG DE, DUMOULINJ.: Neurostimulation électrique transcutanée. Paris : Masson, 1991.