



## IMPROVING THE QUALITY OF LIFE THROUGH EFFECTS OF TREATMENT WITH LOW INTENSITY EXTREMELY LOW-FREQUENCY ELECTROSTATIC FIELD WITH DEEP OSCILLATION® IN PATIENTS WITH BREAST CANCER WITH SECONDARY LYMPHEDEMA TO PATIENTS TREATED WITH STANDARD LYMPH EQUIPMENT.

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### ABSTRACT:

**Objective:** To examine the damaged symptoms and functional disorders in women with secondary lymphoedema after breast cancer surgery in which to evaluate the therapeutic benefits of treatment with low intensity and extremely low frequency electrostatic fields reproduced by the - Deep Oscillation® with the program for a manual lymphatic drainage.

**Methods:** Twenty-one patients, divided into two randomized groups. The first group of women consists of 11 women treated with 10 session's lymphatic drainage with Deep Oscillation. And second control group included 10 women having undergone only standard lymphatic drainage. Subjective assessment includes pain and swelling; range of motion in the shoulder joint; movement of the neck and an analysis of the volume of the chest using a 3D system measuring.

**Results:** At the beginning of therapy, patients had high scores for sensation of pain; swelling of the extremities; restricted movement in the shoulder joint; restriction in the movement of the spine in the neck portion. In the course of treatment the pain reduces its intensity, the volume of movement in the shoulder joint is returns, but in the study group, which is subjected to lymph drainage with low-frequency electrostatic fields of apparatus - Deep Oscillation® indicators are much better. Moreover, significantly pain reduces. Subjective reduce swelling in both groups was confirmed objectively by 3D measuring only in the treatment group.

**Conclusion:** Manual lymph drainage with deep oscillation leads to a significant reduction in pain relief and reduce swelling in patients with lymphoedema average breast compared with standard mechanical lymphatic drainage.

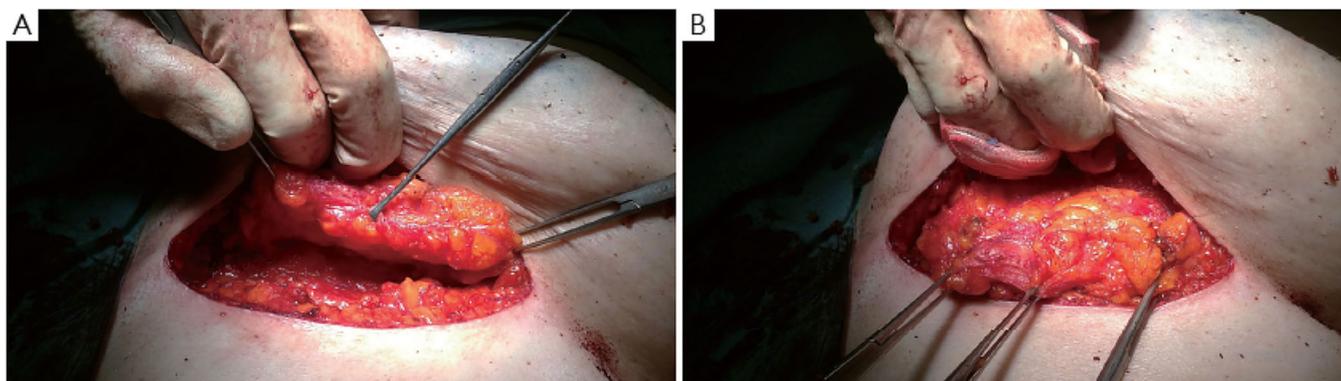
**Keywords:** breast cancer, pain, swelling, lymphatic drainage, low intensity and low frequency electrostatic fields,

### INTRODUCTION:

Specialized Hospital for Rehabilitation - Banya, Karlovo District is the only health institution on the territory of the country where the Physical and Rehabilitation Program for women operated on breast carcinoma is successfully developed. The program is 10 days and is held in groups of 8 women. It is performed by a multidisciplinary team of specialists that includes: Physicians in physical and rehabilitation medicine; physiotherapists (kinesiotherapists, rehabilitation therapists, occupational therapists); oncologists; dieticians; clinical psychologists, and art-therapists.

Patients undergoing organ sparing surgery interventions respond by amplification of the breast fibrosis, i.e. fibrosis of the skin. Goffmann and others. [1] detect breast lymphoedema in 9.8% of their patients. They formulate a definition for breast lymphoedema: swelling of the breast and formation of "orange peel" skin, combined with the sensation of heaviness and pain. The largest study included 160 patients conducted by Rönkä and others [2]. The authors found breast swelling in 34% of the patients, orange skin in 3.8%, and sensitivity to palpation of the breast in 59% of the cases. They noticed that the risk of developing lymphedema increases with the severity of axillary trauma in lymph node dissection, namely by increasing the number of the removed lymph nodes under m. pectoralis major.

**Fig. 1.** Quadrantectomy with lymph node dissection



In lymphedema of the breast the patients experience a chronic pain of medium to high intensity, discomfort, which leads to deterioration in their quality of life. Velanovich & Szymanski [3] investigated the quality of life in patients with secondary lymphedema. In their study they reached to the conclusion that a better treatment of the lymphedema is needed to ensure adequate quality of life in the operated patients. The diagnosis is usually focused on the lymphedema of the arm while the breast lymphedema recedes into the background. The degree of lymphedema of the arm can be quantitatively reproduced by manually measuring the circumference of the arm. The only objective way to study the lymphedema of the breast is the altered thickness of the skin flap. This parameter, however, is poorly reproducible and unreliable.

The objectives of this study are to examine the damaged symptoms and functional disorders in women with secondary lymphedema after surgical treatment in which to evaluate the benefits of the therapeutic treatment with low intensity and extremely low frequency electrostatic fields reproduced by the apparatus - Deep Oscillation® with a program for performing a manual lymph drainage versus the effect of treatment with a standard apparatus lymphatic drainage technique.

To study the objectives set we established clear inclusion criteria for the test group as criteria in studies: Carlson LE, and others [4] and Moadel AB, et al. [5], namely:

1. Patients who underwent organ sparing surgery due to breast carcinoma, completed active treatment; on adjuvant therapy, 3 months after the surgical treatment at the earliest.
2. Women with classification of the tumor according to TNM as follows: pT1 pN0 M0; pT2 pN0 M0; pT4 pN0 M0, with lymph node dissection L0, without distant metastases M0, i.e. in the 1st; 2nd A, and 3rd A stage.
3. The ten-day treatment period is at least 20 days after radiotherapy, or 10 days after chemotherapy in succession.

Exclusion criteria were:

1. Conducted Deep Oscillation® treatment within 3 months prior to study.
2. Acute inflammation; acute thrombosis; cardiovascular diseases; electronic implant; pregnancy; subjective sensitivity to electrical fields.

To objectify the targeted objectives we created special measurement forms they are in studies Egan MY and others [6] and Eifel P, et al. [7], that include: Scoring VAS for assessment of the pain; lymphatic drainage analysis of the upper limb; Kinesiological analysis of the upper limb for the range of motion in the shoulder joint, as well as for the range of motion in the neck (for reference limits of normal movement we accept the following indicators: lateral flexion at 45°, rotation 60°, anteflexion 40°, retroflexion 30°); 3D measurement of the volume of the operated breast with calliper for craniometry in anthropological research; oncohematological analysis. The indicators are filled on admission and discharge of the patient.

We grouped and evaluated these objective indicators so that we can measure the quality of life of patients in absolute values analogically to our earlier article about the quality of life in patients operated for breast cancer after rehabilitation in the Specialized Hospital for Rehabilitation - Banya, Karlovo District.

#### **MATERIALS AND METHODS:**

Deep Oscillation® is a therapeutic approach which consists in applying intermittent electrostatic field of low intensity ( $U = 100-400V$ ;  $I = 150\frac{1}{4}A$ ) and extremely low frequency (30-200Hz, biphasic rectangular) to the target zone. The electrostatic field attracts and releases the patient's tissue in the selected frequency, resulting in deep and permanently resonant vibrations. When the patient and the therapist are connected to the Deep Oscillation® device, serving as a voltage source of high internal resistance, a special glove serves as an insulator. The impulse of the voltage causes an electrostatic force of attraction of the tissues and leads to a higher frictional force while the swelling is massaged. Each session is for the duration of 30 minutes, starting with 15-minute procedures.

At this point we should clarify the principle and the effect of the action of Deep Oscillation® which are expressed in two aspects.

The first aspect - the ability to relax the edema is due to the deep and lasting vibrations caused by the electrostatic low intensity field, which is acting on the tissue level, and the accumulated toxins and sub-products in the extracellular space are released and drained by the lymphatic system.

The second aspect - the reduction of the swelling is

due to the created electrostatic field, which changes the polarity of the cell membrane, and instead if the chemical influences in a physical way the cell channels, and in its turn this makes them open and release the free radicals and metabolic sub-products accumulated in the cytoplasm of the cell into the extracellular space, from where the lymphatic system picks them up.

The device has the following physical characteristics:

**Fig. 2.** Manual technique with Deep Oscillation®



low intensity  $U = 100-400V$ , low current  $I = 150\frac{1}{4}A$  (about 10 times less than in batteries of our mobile phones) and extremely low frequency 30-200Hz with a biphasic rectangular sinusoid, so that the activation of the cells, either its own, or of eventual metastatic ones is not possible, thus making the therapy with this apparatus in these characteristics safe for patients who underwent surgery due to breast cancer, as well as for other cancer patients.

To achieve the objective measurement in the control group and the test group we fill the obtained results in the table of Quality of Life and compare its absolute values.

The assessment of each criterion allows for the objective inclusion of the patients in the created Total Life Quality Scale. According to it, each criterion can be assessed with

three answers that give – 0; 1 or 2 points. With a score from 0 to 3 points - there is no improvement in the quality of life. With a score from 4 to 7 points the assessment of the improvement in the quality of life is “Good”. “Very good” is the assessment of the improvement in the quality of life with a score from 8 to 10 points.

**Table 1.** TLQ scale and table for determining the Quality of Life in women who underwent oncological surgery due to breast cancer.

N	CRITERION	INDICATOR	SCORE
1	Pain Severity (VAS)	Mild pains 0-4	0
		Moderate pains 5-7	1
		Severe pains 8-10	2
2	Swelling of the limb	No change	0
		Functional improvement	1
		Functional and cosmetic improvement	2
3	Range of motion in the shoulder joint	No change – up to 90°	0
		Increase – up to 120°	1
		Increase – over 120°	2
4	Range of motion in the neck	No change	0
		Increase – up to 45°	1
		Increase – over 45°	2
5	3D anthropological measurement of the volume of the breast	No change	0
		Reduction in one size	1
		Reduction in two sizes	2
<b>TOTAL:</b>			

## RESULTS:

The performed study covered 21 women with breast cancer. Their ages ranged between 29 and 61 years. The average age was 45 years. Organ sparing surgery – quadrantectomy with lymph node dissection was performed in all patients who are with secondary lymph>edema in the

area of the breast. Surgery on the left breast was performed in nine patients, and the on the right in 12 patients. The mean postoperative time is 2 years and one month. All patients had had adjuvant radiotherapy 4 to 5 months prior to study.

**Table 2.** Stages of the patients included in the study according to the TNM classification.

STAGES	TEST GROUP			CONTROL GROUP		
	TNM-classification	Number	%	TNM-classification	Number	%
I	pT1 pN0 M0	7	96%	pT1 pN0 M0	9	90%
IIA	pT2 pN0 M0	3	3.1%	pT2 pN0 M0	1	10%
IIB	pT4 pN0 M0	1	0.9%	pT4 pN0 M0	-	0 %

1. The evaluation of the moderate pain and the severity in all patients in both groups was 4.9 based on a visual analogue scale (VAS). The result of swelling is 5.9. There were no significant differences between the two groups.

2. The lymph stasis of the upper extremity homolateral occurred in all the 11 operated women. The conducted low intensity and extremely low frequency electrostatic fields reproduced by the apparatus - Deep Oscillation® with program for performing a manual lymph drainage after instructions of the oncologist at the 11 patients with lymph stasis has led to 100% improvement in all of them. In 2, 18.5% of the cases a reduction in the circumference of the affected limb with 1 cm is observed – functional improvement, and in the rest 9 women, the 81.5% reduction in the swollen limb is by 1.5 to 3 cm, thus proportionality in the both limbs has been achieved – functionally and cosmetically.

3. Increase in the range of motion in the affected shoulder joint of up to 50% was observed in 2 patients, 18.5 %, and in 9 women, 81.5% and over 50% - which led to reference values of the motion in the joint.

4. The mobility in the neck area is impaired in all patients. Only in the test group after the administration of the Deep Oscillation® this lead to a significant reduction in the pain.

5. The subjective sensations of reduce in the swelling in both groups was confirmed objectively by the 3D measurement only in the group treated with Deep Oscillation®

After analyzing the results achieved according to the TLQ-scale in the test group 1 female, 0.9% is with “Good” improvement in her quality of life, while the other 10 women, 99.1% are with “Very Good” improvement in their quality of life. The results in the control group are 3 women, 30% with “Good” improvement in their quality of life, while the other 7 women, 70% are with “Very Good” improvement in their quality of life. We have not had patients with no improvement in their quality of life.

We attribute the differences mainly to the fifth indicator, namely the change in the volume of the lymphedema breast in the test group, which was influenced by therapeutic low-intensity and extremely low frequency

electrostatic fields, while on the control group a standard vacuum-machine lymph drainage was applied only in the area of the affected unilateral for operation upper limb.

## CONCLUSIONS:

The Psychosocial Rehabilitation Program of the Specialized Hospital for Rehabilitation – Banya, Karlovo District with the participation of precise specialists, working in a team and in the underlying consistency of work and consultations with the women operated for breast cancer leads to:

- Influenced the negative effects of the chemo- and radiotherapy.
- Improving the physical activity of the affected upper limb, the general physical activity, and the overall condition of the body.
- Improvement in muscle tone and the muscle strength. Improvement of the affected fine movements of the hand and the fingers.
- Disappearance of the heaviness and pain in the hand, erysipelas of the affected limb.
- In the therapeutic treatment of low intensity and extremely low frequency electrostatic fields reproduced by the apparatus - Deep Oscillation® with a program for performing a manual lymph drainage both the burden and the pain disappeared, as well as the erysipelas of the affected breast and its lymph stasis.

The increase in the quality of life in the test group takes precedence over the increase in the quality of live in the control group. The difference is due to the administered therapy with low intensity and extremely low-frequency electrostatic fields versus a standard vacuum-machine lymph drainage in the control group.

The apparatus used in the study is of innovative nature to our country, but our team will continue to work in this direction while we will gradually cover larger groups of patients while safe keeping their health and in the name of the better and modern treatment. The performed study and evidence material support the improvement of the quality of life of patients with breast carcinoma after treatment under the Physical and Rehabilitation Program of the Specialized Hospital for Rehabilitation – Banya,

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