



## ETUDES CLINIQUES

[www.mtec-company.com](http://www.mtec-company.com)

## **MULTI CENTRE STUDY OF DEEP VEIN THROMBOSIS BY LYMPHAVISION THERAPY**

\*Dr. Yash Gulati, \*\* Prof. B.K. Dhaon, \*\*\* Prof. S. Bhan, \*\*\*\* Dr. S. Agarwal

Prevalence of Deep Vein Thrombosis in India patients has been a matter of debate among Orthopaedic Surgeons. In the absence of authentic studies, opinions given are anecdotal. Some surgeons would believe that incidence is minimal where as others believe that it is as high as in western population. Incidence of fatal Pulmonary Embolism following Orthopaedic surgery, although low, is not significant.

Figures from other Asian countries would suggest that DVT is common in post-operative period. Incidence range from 4% (Chummjarekji, Thailand), 7% (Nandietal, China), 12% (Cunniughem et al., Malaysia, 15.3% (Kiyoshi Inada et al., Japan).

DVT is an important cause of morbidity and fatal pulmonary embolism.

Thrombo prophylaxis is not only desirable but also mandatory in patients undergoing major Orthopaedic Surgery.

Thrombo prophylaxis can be achieved by both pharmacological and non pharmacological means. The most commonly used measures are low-dose or adjusted-dose unfractionated heparin, low molecular weight heparin, oral anticoagulants and compression stockings. Other less commonly used methods are aspirin and intravenous dextran.

Anticoagulants can induce bleeding and need monitoring especially when heparin is used. Low molecular weight heparin is safer but still has the risk of inducing bleeding.

Also, there are situations where anticoagulant therapy may be unsafe. In patients with Polytrauma, orthopaedic surgical intervention may have to be delayed by several days due to associated cranial bleed, hemothorax or abdominal injuries. In such situations major fractures and forced recumbency may be potent factors increasing the risk of DVT with associated probems.

Yet, anticoagulant therapy may not be possible. In such circumstances, availability of reliable non pharmacological method to prevent DVT would be a boon.

This study was undertaken to assess the effectiveness of Lymphavision in prevention of DVT in patients operated for Total Knee Replacement, Total Hip Replacement, Major Spine Surgery involving Instrumental Spinal Fusion and Polytrauma with lower limb fractures.

Study was conducted in a 4 independent hospitals i.e. All India Institute of Medical Sciences, New Dehli L.N.J.P. Hospital, New Dehli, Sant Parmanand Hospital, New Dehli, and Indraprashta Apollo Hospital, New Dehli. First two hospital mentioned above are the largest public hospitals in India and Apollo Hospital is the 4<sup>th</sup>. largest corporate hospital in the world.

Lymphavision current reproduces the autonomic sympathetic nervous system message sent to smooth muscles located between the applied electrodes, thus activating natural peristalsis. Stimulation of the striated muscles allows for a mechanical pumping action by these muscles.

Total of 100 patients were treated with Lymphatic Stimulation in post-operative period.

Total Knee Replacement	-	50
Total Hip Replacement	-	25
Instrumented Spinal Fusion	-	10
Polytrauma with lower limb fractures	-	15

**Hospital** **No. of Patients**

AIIMS	-	25
LNJP	-	25
Sant Parmanand	-	10
Apollo Hospital	-	40
	_____	
Total	=	100

**Sex** **No. Of Patients**

Male	:	35
Female	:	65

**Age** **No. of Patients**

20-30yr.	-	06
30-40yr.	-	08
40-50yr.	-	13
50-60yr.	-	08
60-70yr.	-	45
Above 70yr.	-	20

**Weight** **No. of Patients**

50-60kg	-	13
60-70kg	-	40
70-80kg	-	35
Above 80kg	-	12

## **Methodology**

- Detailed medical history was taken
- Patient with prior history of DVT or history of chronic edema were not included in the study
- Patient were demonstrated the procedure pre-operatively
- No pharmacological prophylaxis was given
- Lymphavision therapy was started on the day of surgery and was continued for 7 to 10 days post op depending on the duration of hospital stay.
- Small rubber pads were applied to the calves of the patients. Low voltage current was delivered to an intensity that slight muscle twitch could be seen. Intensity was kept in comfort zone for patients
- Treatment was given for 30 minutes once a day.
- Calf Girth was measured pre-op, and daily till date of discharge.
- Color Doppler study for both lower limb veins was done pre-op, 4 days post op and 2 weeks post op.
- Clinical symptoms like calf pain (if any) was noted.
- Clinical examination to assess absence or presence of DVT was done on regular basis.
- Patients were mobilized 48 hours post op in case of Total Knee Replacement, Total Hip Replacement and Instrumental Spinal Fusion. Mobility in Polytrauma cases was commenced on individual merit.

## **Observations**

- Current was applied with an intensity of 21 +/- 6.4 mA
- Number of treatment was 7 to 10 (one treatment per day on average)
- Duration of treatment was between 30 minutes / once a day
- Patients showed decrease in Calf Girth from 0.5 cm to 2 cm (average 1.24 cm)
- Patients with Total Knee Replacement had increase Calf Girth in immediate post-operative period by an average of 1.72cm. These patients showed maximum decrease in Calf Girth (average 1.43cm) after 10 days.
- Patients following Total Hip Replacement had increase Calf Girth (average 0.57 cm). These patients showed decrease Calf Girth (average 0.57) in 10<sup>th</sup>; post operative day.
- Patients with Polytrauma with lower limb fractures showed increase Calf Girth (average 2.53 cm). These patients showed decrease Calf Girth (average 1.73 cm) on 10<sup>th</sup>. post operative day.
- Color Doppler study was done on day 0 (pre op day). Day 4<sup>th</sup> post op & Day 14 post op. Study was done for Popliteal, Superficial femoral and common femoral veins.
- Patients of Instrumented Spinal Fusion did not show significant increase in Calf Girth in post op period.
- None of the patients showed evidence of Deep Vein Thrombosis in Post operative period
- None of the patients developed Pulmonary Embolism;

## **Discussion**

Lymphavision Accelerates venous return from lower limbs significantly (Wells et al, University of Ottawa, Canada). Although in the present study, venous flow velocity was not measured, absence of Deep Vein Thrombosis in all the patients would suggest that venous stasis was prevented and venous flow accelerated.

None of these patients received pharmacological thrombo prophylaxis. Absence of DVT would strongly suggest that Lymphavision is useful in prevention of DVT.

Significant reduction of Calf Girth was noticed in patients following Total Knee Replacement, Total Hip Replacement & Polytrauma involving lower limb fractures '1.24 cm average)

Contraction of skeletal muscles provokes a muscular pump effect helping in the reduction of edema. Current reproduces the autonomic nervous system message sent to the smooth muscles located between 2 contact electrodes, thus stimulating natural peristalsis. Smooth muscles are found in practically whole lymphatic system. Low intensity current promotes better lymphangion motility. It leads to relief of spasms of peripheral arteries, normalization of venous outflow, antiedemic and anti-inflammatory effects (Lyubarsky et al, Research Institute of Clinical & Experimental Lymphology, The Siberian Department of Russian academy of Medical Science).

In the present study Calf Girth decreased by 1.24 cm on an average. Mechanism mentioned above may be responsible for rapid reduction of limb edema. Reduction of edema is very helpful in early rehabilitation of patients following surgery.

## **Conclusion**

Absence of DVT in the patients treated by Lymphavision in present study indicates that this may be a very useful non pharmacological tool for prevention of DVT following Total Knee & Total Hip Replacement without the ill effects of anticoagulant therapy.

It may be especially useful in prevention of DVT in Polytrauma patients with head injury, hemothorax or abdominal bleed along with lower limb fractures where anticoagulant may be contra indicated for DVT prophylaxis.

\*Sr; Consultant Orthopaedic Surgeon  
Apollo Hospital, New Dehli

\*\*Head of Dept, LNJP Hospital &  
Dean, Maulana Azad Medical College

\*\*\*Prof & Head, Department of Orthopaedics  
All India Institute of Medical Sciences

\*\*\*\*Director, Sant Parmanand Hospital

\*Dr. Yash Gulati, \*\* Prof. B.K. Dhaon, \*\*\* Prof. S. Bhan, \*\*\*\* Dr. S. Agarwal



## **ROLE OF HIVAMAT® 200 (DEEP OSCILLATION) IN THE TREATMENT OF THE LYMPHEDEMA OF THE LIMBS.**

GASBARRO V, BARTOLETTI R\*, TSOLAKI E, SILENO S, AGNATI M., CONTI M. \*\*, BERTACCINI C.\*\*

O.U. OF VASCULAR AND ENDOVASCULAR SURGERY S.ANNA UNIVERSITY HOSPITAL FERRARA.

\* FONDAZIONE FATEBENEFRATELLI, ROMA

\*\* TERME DI CASTROCARO (FC)

### **Abstract**

#### **Background**

The important goals achieved by the biomedical technologies lead us to search new mechanisms to contribute to the treatment of lymphatic pathologies. The aim of our study is to examine a new instrumental physiotherapeutic method characterized by the utilization of intermittent electrostatic fields with deep oscillation.

#### **Methods**

HIVAMAT® 200 operates at the level of the connective tissue using a pulsing electrostatic field, producing an intense resonant vibration within the tissues involved. The repetition of this phenomenon in rapid succession generates rhythmic deformations of the tissue. This action permits fibre and tissue layers to reacquire motricity and malleability. Upon these premises we conducted a clinical and instrumental study in order to verify its efficacy in the treatment of lymphedemas of the limb. From May to December 2005, 20 patients affected by lymphedema of the limbs underwent treatment with HIVAMAT® 200 in conjunction with II class elastic stockings.

#### **Results**

The results obtained in 20 patients confirmed that this method can have an important role in the treatment of such a complex disease. We achieved a statistically significant reduction in the circumference of the limbs and in the thickness of the subcutis.

#### **Conclusion**

The advantage of HIVAMAT® 200 lies in the combination of electricity and the various techniques of manual massage, thereby improving the results and the quality of treatment. Moreover, due to the potential for self-treatment, it is also possible to offer an on-going domestic therapy.

c

## **ROLE OF HIVAMAT® 200 (DEEP OSCILLATION) IN THE TREATMENT OF THE LYMPHEDEMA OF THE LIMBS.**

GASBARRO V, BARTOLETTI R\* , TSOLAKI E, SILENO S, AGNATI M., CONTI M. \*\*, BERTACCINI C.\*\*

O.U. VASCULAR AND ENDOVASCULAR SURGERY S.ANNA UNIVERSITY HOSPITAL FERRARA.

\* FONDAZIONE FATEBENEFRATELLI , ROMA

\*\* TERME DI CASTROCARO (FC)

### **Introduction**

Lymphedema represents a chronic, inevitably progressive, and invalidating disease from a physical, functional and psychological point of view. For this reason, it requires a targeted approach, early diagnosis, and comprehensive follow up procedures. The crucial difference between the lymphedema with respect to the other vascular edemas is defined by its constant progression in fibrosis. This is because lymphedemas have higher concentrations of proteins and these are responsible for the activation of the chain of inflammation (1).

Clinically, the more the element of inflammation is present, the more the lymphedema goes against connectivization and therefore fibrosis.

Definition of the causes of the lymphatic disease and its evolutive state, are also crucial elements to determine the timing and the methods of the therapeutic strategy (2,3). From the rehabilitative perspective this utilizes well-proven physiotherapeutic techniques which have been tested by numerous clinical studies in the university and medical sector (see guide lines CIF-2004 and CONSENSUS DOCUMENT ISL-2003) (4,5,6,7). All together they correspond to the Complex Decongestive Physiotherapy (CDP) in 2 phases of lymphedema, based on hygienic measures, skin cures, manual lymph drainage (MLD), compressive bandage application and decongestive exercises (8,9).

The aim of our study is to examine a new instrumental physiotherapeutic method characterized by the utilization of intermittent electrostatic fields with deep oscillation.

HIVAMAT® 200 operates at the level of the connective tissue by a pulsating electrostatic field that generates an intense resonant vibration within the tissues involved. The mechanism is based on the creation of a semiconductor layer and a minimal electrostatic field between the hands of the therapist and the tissue of the patient. The repetition of this phenomenon in rapid succession generates rhythmic deformations of the tissue, which is being pumped throughout its entire depth. This action permits fibre and tissue layers to reacquire moticity and malleability and improve tissue nourishment (increased production of ATP). HIVAMAT® 200 acts principally on intercellular circulation at the level of the interstitial connective tissue. The effect of this treatment is the re-stabilization of the fluidity of circulation.

### **Materials & methods**

From May to December 2005, 20 patients affected by lymphedema of the limbs underwent treatment with HIVAMAT® 200 in conjunction with II class elastic stockings. There were 16 females and 4 males with a mean age of between 30 and 60 years.

HIVAMAT® 200 was applied following the procedures of manual lymph drainage (MLD), which consists of the following phases: preparation of the central and peripheral lymph

node stations, and then the successive drainage to lymph centres following the ways of lymphatic flow focusing on the areas of major lymph accumulation. The duration of treatment was 30 minutes, twice a week. Finally, every treatment was subdivided in 2 phases utilizing initially medium-high frequencies (25-80 Hz, 80-200 Hz) dissolving indurated tissue and stimulating the transportation of liquids, followed by low frequencies (25-80 Hz) characterized by a strong pumping effect and thus an effective interstitial drainage. After treatment the elastic stocking was applied on the affected limb.

As inclusion criteria of the study we considered the clinical conditions and the ecographic examination made by the PHILIPS iu22 (10). Measurements of the circumferences of the limbs were made at 3 precise levels: above the ankle, at the upper 1/3 segment of the leg, and at the upper 1/3 segment of the thigh. For every patient such levels were determined by also considering the height from the ground, in order to have a constant and precise level of measurement. At the same levels ecographic examination was performed in order to evaluate morphology and thickness of the subcutis before and after treatment. In this way

we were able to evaluate qualitative modifications of the edema: the grade of edema, the state of connectivization of the subcutis and the presence of fluid lymph accumulation.

Moreover we excluded from the study all patients which were under edema specific or not pharmacological treatment. And we included patients which had finished a complex physical treatment at least 40 days before, in order to not evaluate patients that could have long-term benefits after an intensive treatment.

## Results

After 8 weeks of treatment utilizing HIVAMAT® 200 and compressive stockings (known to not influence significantly edema's evolution) we evaluated both clinically and ecographically in these 20 patients the variations of the circumferences, the subcutaneous thickness and the qualitative variation of the subcutis layer affected by the lymphedema.

In the evaluation of the circumference at the lower 1/3 segment of the leg before the treatment, we obtained data varying between 22.0 and 32.0 cm with a mean average of 25,9 cm. Measurement after treatment produced an average of 24.9 cm with peaks from 21 to 34 cm.

This average reduction of 1 cm was highly significant in the t student test ( $p<0.001$ ).

Evaluation of the circumferences at the upper 1/3 segment of the leg varied between 36 and 45 cm with a mean average of 39.3 cm. At the end of the therapeutic cycle we obtained values between 35 and 44 cm with a mean average of 38.4. Analysis of this data with the t student test demonstrated that the difference was statistically significant.

At the upper 1/3 segment of the thigh circumferences before treatment varied between 57,00 and 75,00 cm with an average of 63,6 cm. After 8 weeks of treatment that range was between 55,5 and 73,5 cm with an average of 62,0 cm, also significant (Table I).

At the same level where circumferences were measured, we pinpointed ecographic windows in the medial upper and lower 1/3 parts of the leg, and at the upper 1/3 segment of the thigh.

Measurements of the subcutis thickness at the lower 1/3 segment of the leg before treatment had an average of 4.12 cm in a range between 3.50 and 5,09 cm. After treatment this value decreased to 3,97 cm (with a range between 5,41-3,34), again statistically significant ( $p<0.000$ ).

at the upper 1/3 segment of the leg, before treatment, the average subcutis thickness was 6,26 (range between 5,73-7,16 cm). After treatment there was a decrease in thickness to 6,14 cm (a range between 5,57-7,00). This result was not significant.

The final measurement of the subcutaneous thickness was undertaken at the upper 1/3 of the thigh. The average value of the initial thickness was 9,86 (with a range from 8,83 to 11,7). At the end of treatment this was reduced to 9,67 (a range of 7,95-11,3). These results were statistically significant ( $p=0,001$ ) (Table II).

We wanted to undertake a qualitative evaluation of the conditions of the subcutaneous layer and those which were the dominant features: edema, presence of lymphatic pools associated with the presence of lymph at the subcutaneous layer, fibrosis and sclerosis.

In all cases a substantial reduction was observed of the fibrotic component and, if present, of the sovrafascial edema. Clinically, this last result signified a major presence of a tender edema. This outcome allowed us, at the end of our study, to suggest a new intensive treatment to this group of patients. No side effects were observed, neither initially, nor subsequently, in the use of this machine.

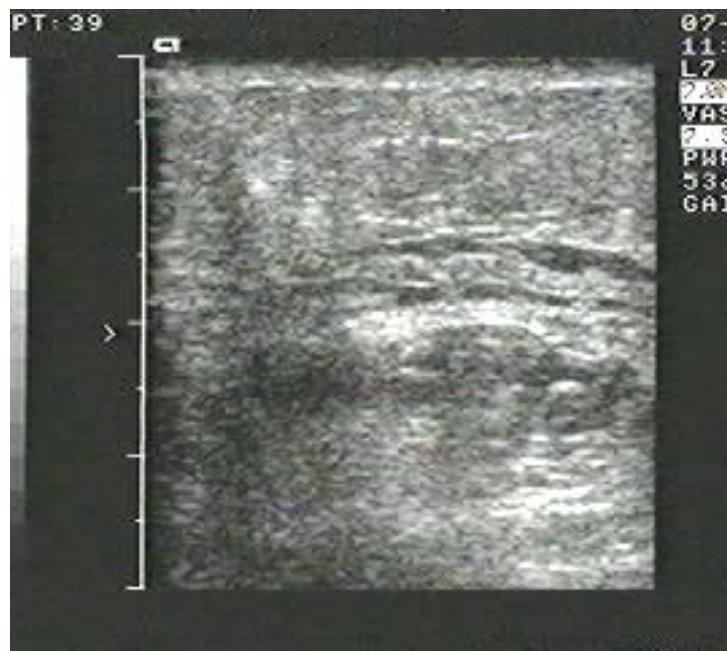


Photo 1: "Ecographic Window" of a Linfoedematous limb with evident connectivization and presence of lymphatic pools.

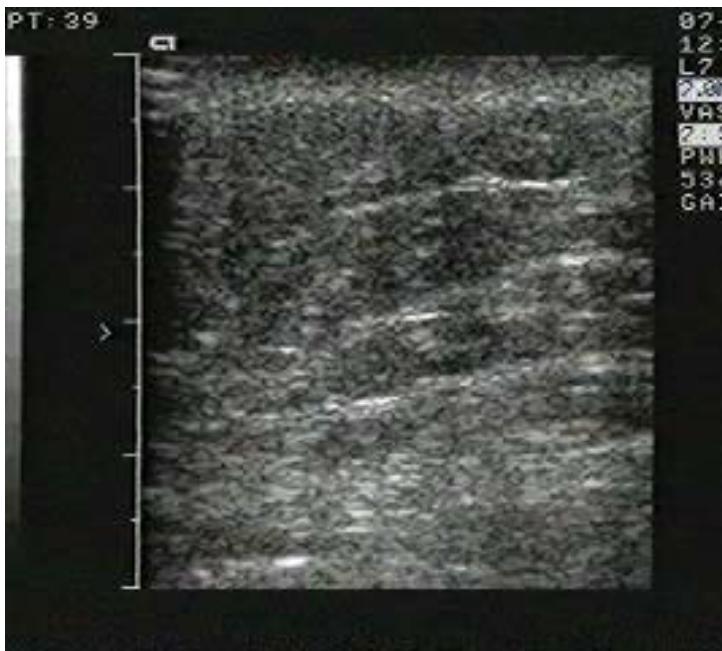


Photo 2: Same “ecographic window” of the previous patient: Evident reduction in the lymph accumulation and in connectivization.

#### Discussion

From the results obtained from our clinical research it is evident that, when confronted with a lymphedema, one cannot expect a clinical resolution of the disease, but only an improvement in the objective and subjective parameters. This aim was accomplished with the application of the deep oscillation method: With the HIVAMAT® 200 we achieved a statistically significant reduction in the circumference of the limbs affected. The type of clinical evaluation used, if applied rigorously, is able to confirm the result of any treatment aimed at improving lymphedemas.

We wanted to add both qualitative and quantitative ecographic evaluations by monitoring the structural aspects of the subcutis. As a result, the ecographic studies have also confirmed that the application of deep oscillation significantly reduces the thickness of the subcutis of the limbs.

Studies that utilize the deep oscillation method on lymphedemas of the limb are not described in the scientific literature. Our experience demonstrated that this treatment can positively influence the evolution of the lymphedematous limb.

#### Conclusions

Lymphedema represents a chronic, irreversible and debilitating condition with an inevitable progression. Instrumental tests are useful to confirm the diagnosis, determine residual lymphatic function, select and evaluate therapeutic methods. The goal of the treatment is to remove stagnating lymph in order to avoid the onset of subcutaneous fibrosis, prevent complications as lymphangitis, severe functional impairment, cosmetic embarrassment and amputation of the limb, and finally improve patient's quality of life. The non-invasive, conservative therapy represents the principal approach for lymphedema. Surgical procedures as lymphovenous anastomosis, are reserved for specific conditions and they are rarely indicated as primary therapeutic option.

The Complex Decongestive Physiotherapy (CDP) of lymphedema is commonly utilized as primary treatment and is based on hygienic measures, skin cures, manual lymph drainage (MLD), compressive bandage application and decongestive exercises.

HIVAMAT® 200 is a new instrumental physiotherapeutic method characterized by the utilization of intermittent electrostatic fields with deep oscillation stimulating the transportation of interstitial liquids and their components and permitting fibre and tissue layers to reacquire motricity and malleability. All these effects are achieved with a minimal external pressure.

In our experience, 2 to 3 week cycles of CDP constitute the optimum treatment for lymphedema of the limbs. Thus, in association with the deep oscillation method, able to stimulate transportation of interstitial fluids and their components, we can ensure an improvement of the quality of treatment, a reduction in treatment times with positive effects on the costs of patient management and an improvement of patient's quality of life. Furthermore, thanks to the possibility of self-treatment, it is possible to offer therapeutic continuity in the comfort of a patient's home.

## Bibliography

- 1) Allegra C., Bartolo M. jr., Sarcinella R: Morphological and functional characters of the cutaneous lymphatic in primary lymphedema. *Europ. Journ. Lymph.* 1996; 6 (I), 24.
- 2) Gasbarro V, Cataldi A. C.E.A.P. – L. Proposal of a new classification. *The European Journal of Lymphology.* Vol 12., 41,2004
- 3) Gloviczki P, Wahner H.W. Clinical Diagnosis and Evaluation of Lymphedema in Vascular Surgery. IV Edition II. 143; 1899-1920. 1995.
- 4) Guidelines for the diagnosis and therapy of vein and lymphatic disorders. *International Angiology* 2005. Vol 24, 107 – 168.
- 5) Bernas MJ, Witte C.I., Witte M.H. For the ISL Executive Committee. The diagnosis and treatment of peripheral lymphedema. *Lymphology*,2001, (34),84-9.
- 6) Donini I., Vettorello G.F., Gasbarro V. et al. Proposta di Classificazione operativa del linfedema. *Federazione Medica* 12: 381-387; 1995.
- 7) Campisi C. Lymphoedema: modern diagnostic and therapeutic aspects. *International Angiology* 1999;18(1),14-24.
- 8) Földi M., Casley -Smith J.R. *Lymphangiology*. Schattauer. New York; 1983.
- 9) Földi M., Kubik S. *Lymphologie* p 469-526. III Edition, Gustav Fischer Verlag, Stuttgart,1993.
- 10) Pecking A, Cluzan R. Explorations du systeme lymphatique : epreuve au bleu, lymphographies directs, lymphoscintigraphies, autres méthodes. *Encycl Med Chir* (Elsevier, Paris) *Angéiologie*. 1997, 19,1130-5.

Table I

**Measurement of the circumferences of the limb**

<b>SEGMENT</b>	<b>Mean Average before treatment (cm)</b>	<b>Average post treatment (cm)</b>	<b>Range before treatment (cm)</b>	<b>Range post treatment (cm)</b>
Lower 1/3 leg	25,9	24,9	22,0 – 32,0	21,0 – 34,0
Upper 1/3 leg	39,3	38,4	36,0 – 45,0	35,0 – 44,0
Upper 1/3 thigh	63,6	62,0	57,0 – 75,0	55,5 – 73,5

Table II

**Measurement of the subcutaneous thickness**

<b>SEGMENT</b>	<b>Mean Average before treatment (cm)</b>	<b>Average post treatment (cm)</b>	<b>Range before treatment (cm)</b>	<b>Range post treatment (cm)</b>
<b>Lower 1/3 leg</b>	<b>4,12</b>	<b>3,97</b>	<b>3,50 – 5,09</b>	<b>21,0 – 34,0</b>
<b>Upper 1/3 leg</b>	<b>6,26</b>	<b>6,14</b>	<b>5,73 – 7,16</b>	<b>5,57 – 7,00</b>
<b>Upper 1/3 thigh</b>	<b>9,86</b>	<b>9,67</b>	<b>8,83 – 11,7</b>	<b>7,95 – 11,3</b>

# **HIVAMAT® (DEEP OSCILLATION®) IN THE TREATMENT OF EXCISIONAL WOUNDS**

**(EXPERIMENTAL STUDY)**

Wound Healing Effects of Deep Electrical Stimulation": Mikhalkhik E., Titkova S., Anurov. M., Suprun M.,  
Ivanova A., Trakhtman I., Reinhold, J.  
Dept. Molecular Biology & Dpt. Physiology, Russian State University, Moscow, 2005

**SPLIT THICKNESS EXCISIONAL WOUND MODEL**  
**(The model, regime of DEEP OSCILLATION® exposure, and photographs see in the Power Point files)**

**Wound healing effect.**

**Planimetry results (mm<sup>2</sup>, Mean $\pm$ SD).**

	Intraoperative wound size	4 days after operation	8 days after operation
<b>DEEP OSCILLATION®</b>	<b>856.78<math>\pm</math>43.57</b>	<b>528.47<math>\pm</math>82.71*;**</b>	<b>37.55<math>\pm</math>27.21*;**</b>
<b>CONTROL</b>	<b>851.20<math>\pm</math>62.87</b>	<b>619.62<math>\pm</math>69.62*</b>	<b>140.67<math>\pm</math>79.12*</b>

\*- p<0.05 vs. Intraoperative wound size

\*\*- p<0.05 vs. CONTROL

**Conclusions:** DEEP OSCILLATION® exposure resulted in significant improvement of the wound healing process seen at the 4<sup>th</sup> and 8<sup>th</sup> days afterwounding

**Biochemical effects.**

**CL, whole blood (mV, Mean $\pm$ SD).**

	Before operation	2 days after operation	4 days after operation	6 days after operation	8 days after operation
<b>DEEP OSCILLATION®</b>	<b>8.2<math>\pm</math>2.5</b>	<b>13.8<math>\pm</math>3.3*</b>	<b>12.5<math>\pm</math>4.4*</b>	<b>14.7<math>\pm</math>3.9*</b>	<b>13.8<math>\pm</math>2.3*</b>
<b>CONTROL</b>	<b>8.6<math>\pm</math>2.3</b>	<b>17.7<math>\pm</math>7.7*</b>	<b>14.1<math>\pm</math>5.4*</b>	<b>14.9<math>\pm</math>4.8*</b>	<b>15.1<math>\pm</math>5.3*</b>

\*- p<0.05 vs. Before operation

**Conclusions:** DEEP OSCILLATION® exposure did not affect significantly the free radical production in the circulating blood. Therefore we could suggest it did not have **generalized effects** on the biochemical processes

**MPO, granulation tissue (mkmol/g prot, Mean $\pm$ SD).**

	<b>4 days after operation</b>	<b>8 days after operation</b>
<b>DEEP OSCILLATION®</b>	<b>225.1<math>\pm</math>78.0</b>	<b>196.3<math>\pm</math>2.3</b>
<b>CONTROL</b>	<b>243.9<math>\pm</math>65.1</b>	<b>197.6<math>\pm</math>3.7</b>

**Conclusions:** DEEP OSCILLATION® exposure neither increase nor decrease the recruitment of granulocytes into the granulation tissue. Therefore DEEP OSCILLATION® did not affect the normal process of tissue regeneration.

**MPO, new epidermis (mkmol/g prot, Mean $\pm$ SD).**

	<b>8 days after operation</b>
<b>DEEP OSCILLATION®</b>	<b>60.2<math>\pm</math>6.5*</b>
<b>CONTROL</b>	<b>90.7<math>\pm</math>9.3</b>

\*- p<0.005 vs. CONTROL

**Conclusions:** DEEP OSCILLATION® exposure resulted in the significant inhibition of myeloperoxidase activity in the new epidermis. Therefore we concluded that DEEP OSCILLATION® possessed the anti-inflammatory effect.

**GPx, granulation tissue (un/mg prot, Mean $\pm$ SD).**

	<b>4 days after operation</b>	<b>8 days after operation</b>
<b>DEEP OSCILLATION®</b>	<b>0.75<math>\pm</math>0.15</b>	<b>0.82<math>\pm</math>0.03*</b>
<b>CONTROL</b>	<b>0.75<math>\pm</math>0.11</b>	<b>1.03<math>\pm</math>0.07</b>

\*- p<0.05 vs. CONTROL

**Conclusions:** DEEP OSCILLATION® exposure resulted in significant inhibition of the glutathione peroxidase activity in the granulation tissue that reflected its anti-oxidant and anti-inflammatory action

**GPx, new epidermis (un/mg prot, Mean $\pm$ SD).**

	Before operation	8 days after operation
<b>NORMAL EPIDERMIS</b>	<b>0.35<math>\pm</math>0.11</b>	
<b>DEEP OSCILLATION®</b>		<b>1.09<math>\pm</math>0.15*</b>
<b>CONTROL</b>		<b>0.98<math>\pm</math>0.17*</b>

\*- p<0.05 vs. NORMAL EPIDERMIS

**Catalase, granulation tissue (mkg/mg prot, Mean $\pm$ SD).**

	4 days after operation	8 days after operation
<b>DEEP OSCILLATION®</b>	<b>9.02<math>\pm</math>5.67</b>	<b>9.76<math>\pm</math>3.32</b>
<b>CONTROL</b>	<b>10.26<math>\pm</math>2.85</b>	<b>5.55<math>\pm</math>2.71</b>

**Catalase, new epidermis (mkg/mg prot, Mean $\pm$ SD).**

	Before operation	8 days after operation
<b>NORMAL EPIDERMIS</b>	<b>22.03<math>\pm</math>5.09</b>	

DEEP OSCILLATION®		<b>19.81<math>\pm</math>5.06**</b>
CONTROL		<b>11.47<math>\pm</math>5.26*</b>

\*- p<0.05 vs. NORMAL EPIDERMIS

\*\*- p<0.05 vs. CONTROL

**SOD, granulation tissue (un/mg prot, Mean $\pm$ SD).**

	<b>4 days after operation</b>
DEEP OSCILLATION®	<b>2.99<math>\pm</math>0.04</b>
CONTROL	<b>3.46<math>\pm</math>0.66</b>

**SOD, new epidermis (un/mg prot, Mean $\pm$ SD).**

	<b>Before operation</b>	<b>8 days after operation</b>
NORMAL EPIDERMIS	<b>2.44<math>\pm</math>1.32</b>	
DEEP OSCILLATION®		<b>2.76<math>\pm</math>0.78</b>
CONTROL		<b>2.68<math>\pm</math>1.39</b>

**Antiedematous effect.**

**Ratio of tissue weight to dry tissue weight, granulation tissue (g/g, Mean $\pm$ SD).**

	<b>4 days after operation</b>
<b>DEEP OSCILLATION®</b>	<b>1.977<math>\pm</math>0.213*</b>
<b>CONTROL</b>	<b>2.398<math>\pm</math>0.266</b>

\*- p<0.05 vs. CONTROL

**Conclusions:** DEEP OSCILLATION® exposure significantly decreased swelling in the wounded area therefore the ratio of dry to wet tissue weight dropped statistically significant

## FULL THICKNESS EXCISIONAL WOUND MODEL

**Wound healing effect.**

**Planimetry results (mm<sup>2</sup>, Mean $\pm$ SD).**

	Intraoperative wound size	4 days after operation	8 days after operation
<b>DEEP OSCILLATION®</b>	<b>418.42<math>\pm</math>22.23</b>	<b>178.43<math>\pm</math>20.54*;**</b>	<b>50.9<math>\pm</math>11.45*;**</b>
<b>CONTROL</b>	<b>418.61<math>\pm</math>17.17</b>	<b>241.11<math>\pm</math>42.31*</b>	<b>82.93<math>\pm</math>14.09*</b>

\*- p<0.05 vs. Intraoperative wound size

\*\*- p<0.05 vs. CONTROL

**Conclusions:** DEEP OSCILLATION® exposure resulted in significant improvement of the wound healing process seen at the 4<sup>th</sup> and 8<sup>th</sup> days after wounding

**Biochemical effects.**

**CL, whole blood (un, Mean $\pm$ SD).**

	Before operation	2 days after operation (before procedure)	2 days after operation (after procedure)
DEEP OSCILLATION®	<b>8.7<math>\pm</math>4.5</b>	<b>15.5<math>\pm</math>5.8</b>	<b>32.7<math>\pm</math>9.4*,**</b>
CONTROL	<b>8.7<math>\pm</math>4.5</b>	<b>19.7<math>\pm</math>5.3*</b>	<b>37.6<math>\pm</math>9.6*,**</b>

\*- p<0.05 vs. Before operation

\*\*- p<0.05 vs. Before procedure

**Conclusions:** DEEP OSCILLATION® exposure did not affect significantly the free radical production in the circulating blood. Therefore we could suggest it did not have **generalized effects** on the biochemical processes

**MPO, edge of wound (mkmol/g prot, Mean $\pm$ SD).**

	Before operation	4 days after operation	8 days after operation
NORMAL SKIN	<b>110.6<math>\pm</math>55.4</b>		
DEEP OSCILLATION®		<b>180.9<math>\pm</math>42.3**</b>	<b>201.7<math>\pm</math>94.8**</b>
CONTROL		<b>293.8<math>\pm</math>32.9*</b>	<b>360.5<math>\pm</math>146.8*</b>

\*- p<0.05 vs. NORMAL SKIN

\*\*- p<0.05 vs. CONROL

**Conclusions:** DEEP OSCILLATION® exposure resulted in the significant inhibition of myeloperoxidase activity in the wound. Therefore we concluded that DEEP OSCILLATION® possessed evident anti-inflammatory effect.

**MDA, edge of wound (mkmol/g prot, Mean $\pm$ SD).**

	Before operation	4 days after operation	8 days after operation
<b>NORMAL SKIN</b>	<b>0.47<math>\pm</math>0.07</b>		
<b>DEEP OSCILLATION®</b>		<b>0.52<math>\pm</math>0.11**</b>	<b>0.58<math>\pm</math>0.13</b>
<b>CONTROL</b>		<b>0.86<math>\pm</math>0.19*</b>	<b>0.54<math>\pm</math>0.12</b>

\*- p<0.05 vs. NORMAL SKIN

\*\*- p<0.05 vs. CONROL

**Conclusions:** DEEP OSCILLATION® exposure resulted in the significant inhibition of lipid peroxidation in the wound at the 4<sup>th</sup> day. Therefore we concluded that DEEP OSCILLATION® possessed both antioxidant and anti-inflammatory effect.

#### **Antiedematous effect.**

#### **Ratio of tissue weight to dry tissue weight, edge of wound (g/g, Mean $\pm$ SD).**

	Before operation	4 days after operation	8 days after operation
<b>NORMAL SKIN</b>	<b>1.908<math>\pm</math>0.097</b>		
<b>DEEP OSCILLATION®</b>		<b>1.767<math>\pm</math>0.142**</b>	<b>1.921<math>\pm</math>0.192**</b>
<b>CONTROL</b>		<b>2.205<math>\pm</math>0.271*</b>	<b>2.190<math>\pm</math>0.147*</b>

\*- p<0.05 vs. NORMAL SKIN

\*\*- p<0.05 vs. CONROL

**Conclusions:** DEEP OSCILLATION® exposure significantly decreased swelling in the wounded area therefore the ratio of dry to wet tissue weight dropped statistically significant

Tactics of the surgical treatment of the patients with lymphedema of extremities.

A.I. Shevela, M.S. Lyubarsky, O.A. Shumkov, A.V. Evorskaya, V.V. Nimaev, V.A. Egorov

The Institute of the scientific researches of clinical and experimental lymphology  
of the Siberian branch of Russian Academy of medical sciences, Russia  
Novosibirsk, Russia  
E-mail: [shevela@ngs.ru](mailto:shevela@ngs.ru)

The stored experience of lymphedema microsurgical treatment didn't prove its value. The positive experience of using the liposuction for lymphedema treatment of H. Brorson and al. shows the perspective of this method. At the same time on the late stages of the disease it is necessary to recourse to the resection interventions. The purpose of the present experiment is to find out the optimal mode of surgical treatment depending on the disease stage.

The experience of surgical treatment of 132 patients with different forms and stages of lymphedema of upper and lower extremities is examined. Microsurgical methods are used only on the limited number of the patients with the early stages of disease. The resection interventions (of Charles, Homans) are done to the patients after the irrational treatment that caused the marked sclerosis of the skin and soft tissues of the extremities. The combination of endoscopic fasciotomy and liposuction was used to the patients with the lymphedema of extremities after the ineffective conservative therapeutics or microsurgical treatment, mainly on the upper extremities. During the postoperative period the fixed elastic compress was obligatory for all patients. The patients with lymphedema of lower extremities had in addition an electro stimulating therapeutics treatment with the BodyDrain<sup>®</sup> apparatus.

Due to the treatment with the BodyDrain<sup>®</sup> it is achieved the improvement of lymphangion motility, the increase of volumetric and velocity values of lymph flow, the removal of peripheral arterial spasm.

Thus, the surgical treatment tactics depends on the process stage and localization, and on the degree of sclerosis alterations.

## Lymph stimulation for the patients with diabetic foot syndrome

YU. I. Borodin, M.S. Lyubarsky, A.I. Shevela, O.A. Shumkov,  
A.V. Evorskaya,  
V.V. Nimaev, A.A. Rakitin

The Institute of the scientific researches of clinical and experimental lymphology  
of the Siberian branch of Russian Academy of medical sciences, Russia  
Novosibirsk, Russia  
E-mail: [shevela@ngs.ru](mailto:shevela@ngs.ru)

The surgical pyogenic infection that appears on the patients with diabetes is rather difficult to be treated. Parallel with improvement of the peripheral blood circulation, with normalization of the glycemia level, the study of the lymph system reaction at this pathology is of a certain interest. It was observed the reduction of velocity and volume of peripheral lymph outflow of all patients with diabetic foot syndrome. In the standard treatment procedures were included the procedures aimed to stimulate the lymph outflow. We offered the method of stimulation with electro impulses on the BodyDrain<sup>®</sup> apparatus in combination with the injections of mix medicines for lymph stimulation. The direct mechanism of physiotherapeutic procedures with the use of BodyDrain<sup>®</sup> apparatus tends to improve the lymphangion motility, to increase the volumetric and velocity values of lymph flow, to remove the peripheral arteries spasms, to normalize the values of venous outflow, shows the antiedemic, anti-inflammatory action, improves the alimentation of nervous tissue at regeneration, reduces the sclerosis and fibrosis of the tissues and also block the pathologic impulses. The abovementioned methods were used in the course of medical treatment of 52 patients. The use of the BodyDrain<sup>®</sup> apparatus together with the therapeutic vasoactive procedures to the patients with diabetic foot syndrome permitted to reduce the pain syndrome, to improve the state of micro lymph circulation process and in a number of cases to restore tactile sensibility. The control of

wound healing process showed the accelerated wound healing. After the treatment it was registered the increase of velocity of lymph outflow of 17% and of the lymph outflow volume - of 28%.

**ACCELERATED REDUCTION IN LOWER EXTREMITY EDEMA WITH  
POST-OPERATIVE USE OF THE LYMPHAVISION™ IN PATIENTS  
UNDERGOING TOTAL KNEE REPLACEMENT.**

PS Wells, C. McEnery. Ottawa Health Research Institute, the University of Ottawa, Ottawa; Ontario, Canada.

The Lymphavision™ is a device that delivers a low-voltage electrical current, purported to result in stimulation of venous smooth muscles and the lymphatic system. Small rubber pads are applied to the calves of the patients for 20 - 30 minutes two to three times daily. The low-voltage current can be delivered so it is detectable by the patient as a slight muscle twitch. We performed a pilot study in patients undergoing total knee replacement surgery for the first time. Patients with prior DVT or history of chronic edema were excluded. We randomized patients in a two to one allocation, to receive the Lymphavision™ or not, respectively. The two groups were comparable with respect to age and gender. In patients in whom the device was applied, twice daily applications for thirty minutes at a time were employed. After 3 to 6 days we the calf circumference relative to the baseline measurement that was established in the first 24 hours post-operatively. Six of eight patients who had the device applied had 1.0 centimetres or more of edema reduction versus one of four without the device. This pilot study demonstrates the potential for the Lymphavision™ to be useful in the rehabilitation of patients post total knee replacement. Larger patient numbers and more prolonged use of the device will help to determine more accurately the benefit of this device.

## Abstract number: P2264

Supplement to the journal Thrombosis and Haemostasis, July 2001 (ISSN 0340-6245)

# INCREASED VENOUS VELOCITY WITH THE LYMPHAVISION® A NEW DEVICE FOR THE PREVENTION OF DEEP VEIN THROMBOSIS

**P.S. Wells**, M. Rodger, M. Forgie, K. O'Rourke, C. McEnery, C. Leger

*University of Ottawa; Ontario, Canada*

The Lymphavision® is a device that delivers a low-voltage electrical current, purported to result in stimulation of venous smooth muscles and the lymphatic system. Small rubber pads are applied to the calves of the patients for 20-30 minutes two to three times daily. The low-voltage current can be delivered so it is slightly detectable by the patient or more vigorously to induce a slight muscle twitch, the latter preferred by the manufacturer. A similar device has been studied in patients after elective hip arthroplasty. In that study all patients received 7500 units sc of unfractionated heparin bid but only one group received the device. The rate of DVT was reduced by 60% but the study was not blinded, randomization was by the day of the week, and the study was only published in abstract form. Nonetheless these potentially promising results prompted us to test the Lymphavision®. To test the claim that it accelerates venous return from the lower limbs we randomly selected 40 individuals without a prior history of venous or arterial disease for study. Venous velocity was measured by ultrasound with the volunteers in the supine position. In 20 volunteers (intervention group) after a few minutes rest the electrodes were applied to one lower extremity, baseline venous velocity measured and then slight stimulation, not inducing muscle twitch, was applied. After 20 minutes the velocity was again measured and the device turned off. Given that the manufacturer recommends only thrice daily application (i.e. the induced changes are persistent) the volunteers remained supine for another twenty minutes and the velocity was measured for the third time. This group then had the impulse increased to result in a muscle twitch. The same sequence was used in the 20 controls, with the electrodes applied, but the device was not turned on. The volunteers were unaware that the device was not turned on. The results were analyzed using an independent-samples t-test for the different time intervals with the null hypothesis that there would be no difference between the control and treatment groups. The two groups were comparable with mean ages 38 and 36; 74% and 70% females. After 20 minutes the velocity had increased from a mean of 11.5 to a mean of 14.9 in patients with the device and from 15.6 to 15.6 in the controls ( $p = 0.08$ ). After 40 minutes the mean was 14.9 in the intervention group and 15.1 in the control group ( $P = 0.19$ ). However, in the intervention group when the impulse was increased to result in a muscle twitch the venous velocity further increased to a mean of 23.5 ( $p = 0.0042$  compared the result at baseline). The Lymphavision® is a non-pharmacologic method with the potential to prevent DVT. Its application results in a significant increase in venous velocity in the lower extremities. It is possible that it is not necessary to induce the muscle twitch for the device to work but further study is needed. Randomized trials assessing the Lymphavision® for the prevention of DVT should be performed.

## DEEP VEIN THROMBOSIS AND PULMONARY EMBOLISM

©2001 Schattauer GmbH, Stuttgart - New York

All rights reserved.

---

**XVIII Congress**  
**The International Society on Thrombosis and Haemostasis**  
**July 6-12, 2001**  
**Paris, France**

Updated 26 June, 2001

*HIVAMAT IN THE  
TREATMENT OF FULL  
THICKNESS EXCISIONAL  
WOUND*

**EXPERIMENTAL  
INVESTIGATION**

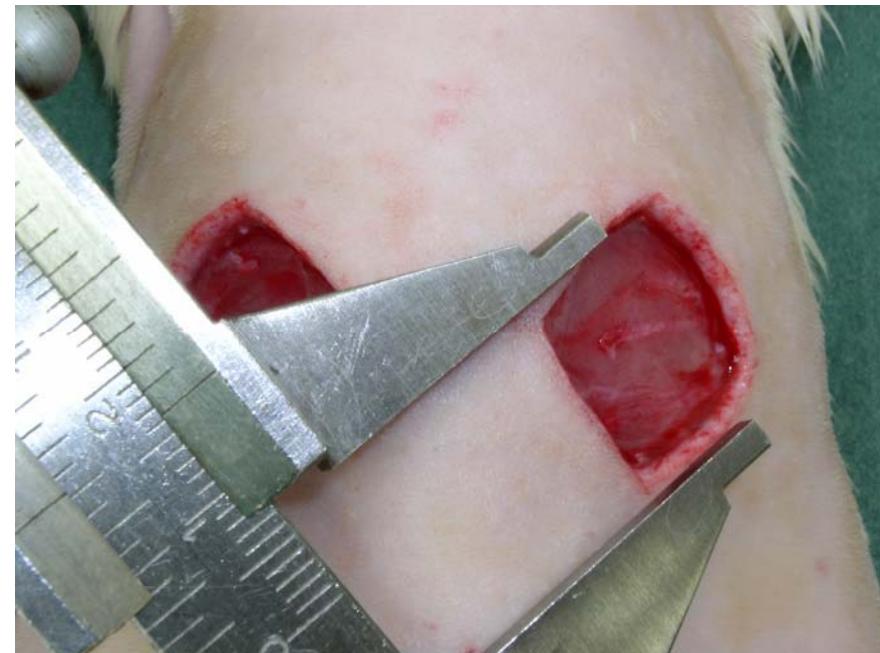
# Full Thickness Excisional Wound Model

---

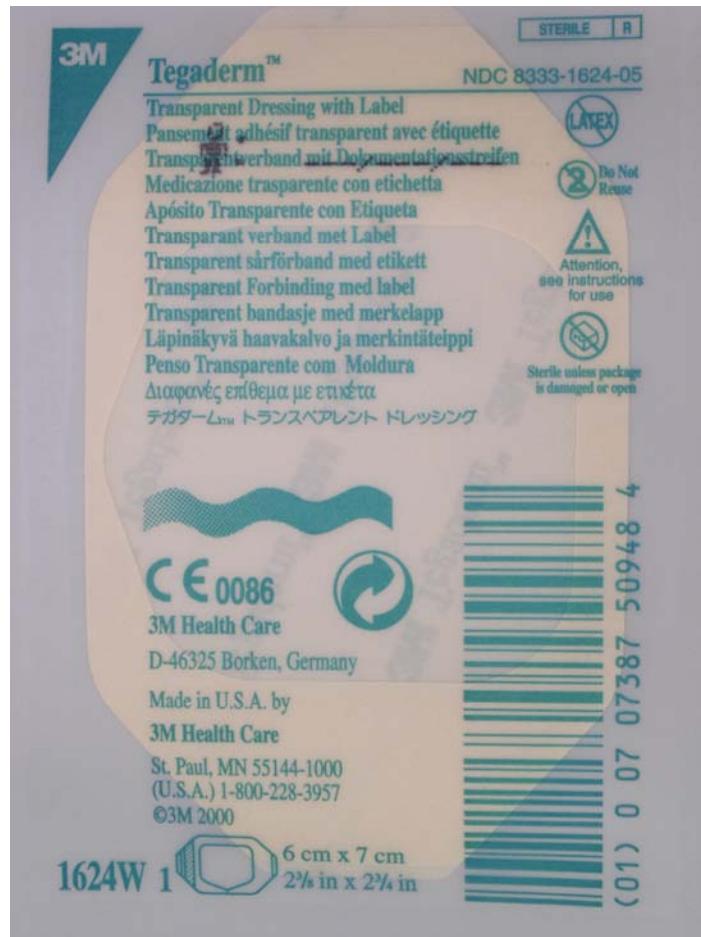


# Full Thickness Excisional Wound Model

---



# Wound Dressing



# Procedure Of The Treatment With HIVAMAT

---

- Therapy with hand applicator
- Frequency: high- 100 Hz and low- 10 Hz in ratio 2:1
- Exposition 3 min



# Investigation Protocol

---

## 4 days after operation:

- Wound planimetry
- Biopsy of the edge of wound for quantitative assessment of edema and biochemical measurements

## 8 days after operation:

- Wound planimetry
- Biopsy of the edge of wound for quantitative assessment of edema and biochemical measurements

# Planimetry

---



4 days after operation



8 days after operation

# Tissue Biopsy

---



4 days after operation



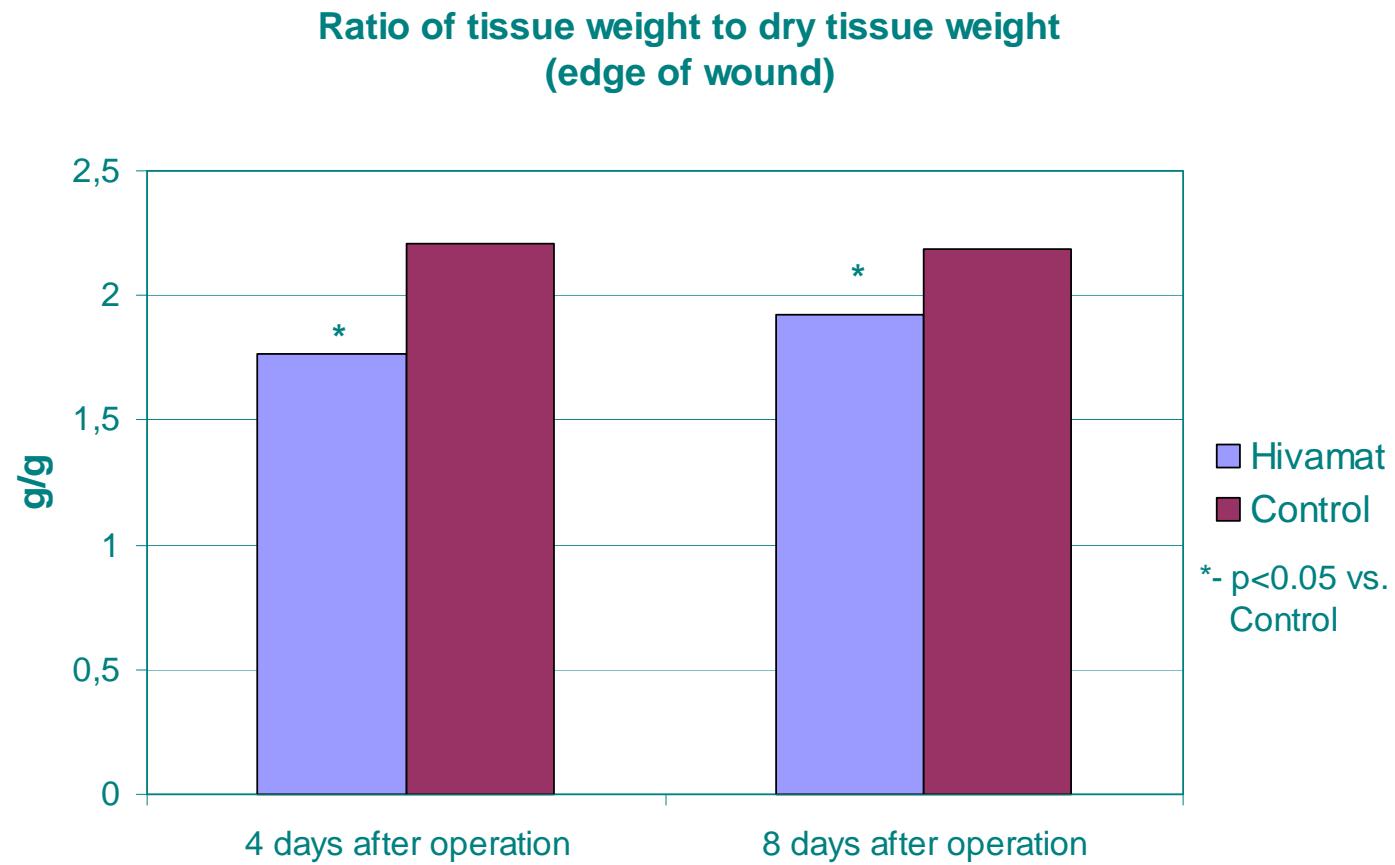
8 days after operation

# Effects Of The Treatment

---

- **Anti-edematous**
- **Anti-inflammatory**
- **Wound Healing**

# Anti-Edematous Effect



# Anti-Edematous Effect

*(4 days after operation)*

---



HIVAMAT



CONTROL

# Anti-Edematous Effect

*(8 days after operation)*



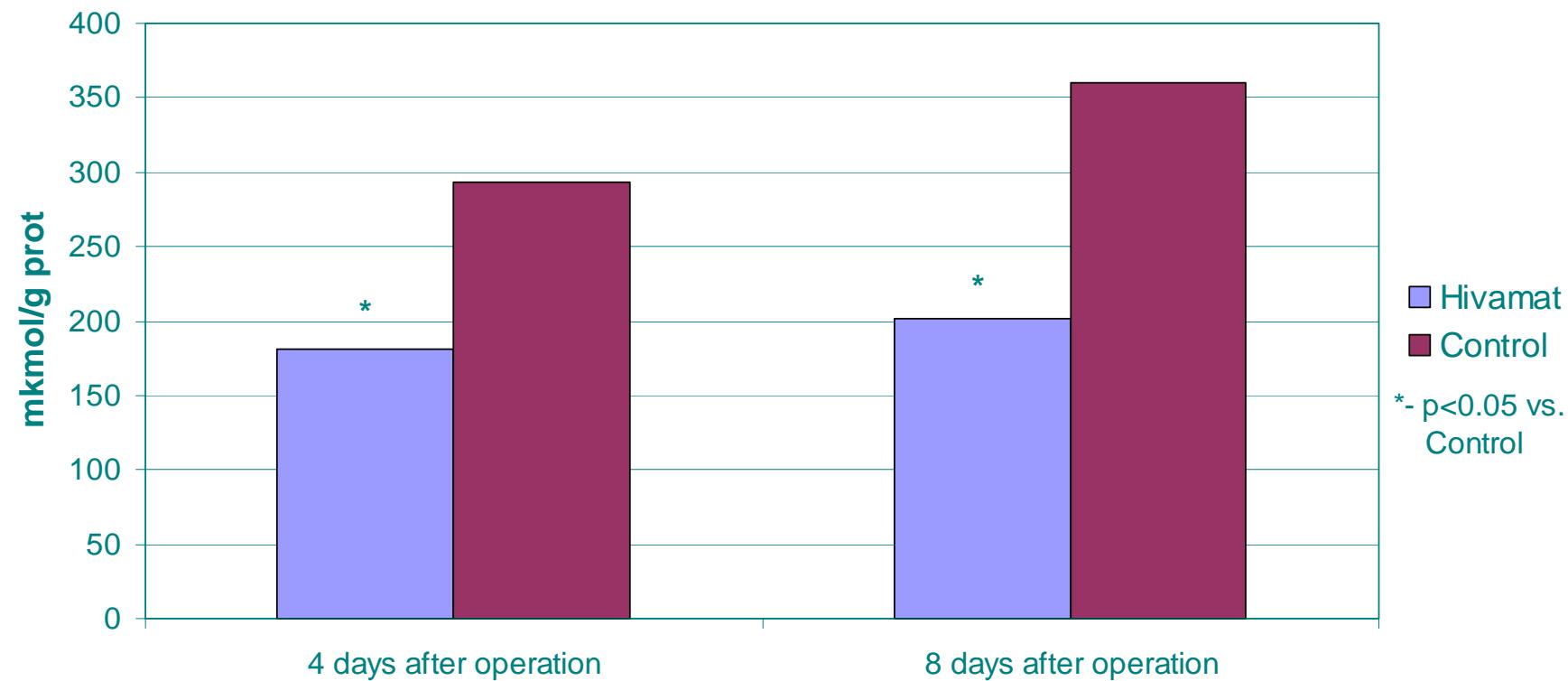
HIVAMAT



CONTROL

# Anti-Inflammatory Effect

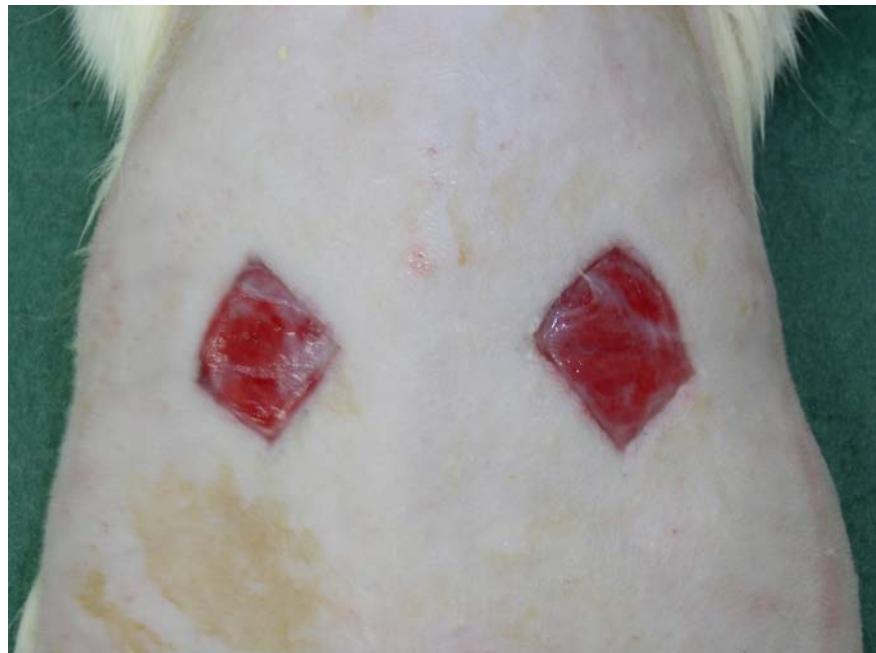
MPO, edge of wound



# Anti-Inflammatory Effect

*(4 days after operation)*

---



HIVAMAT



CONTROL

# Anti-Inflammatory Effect

*(8 days after operation)*

---



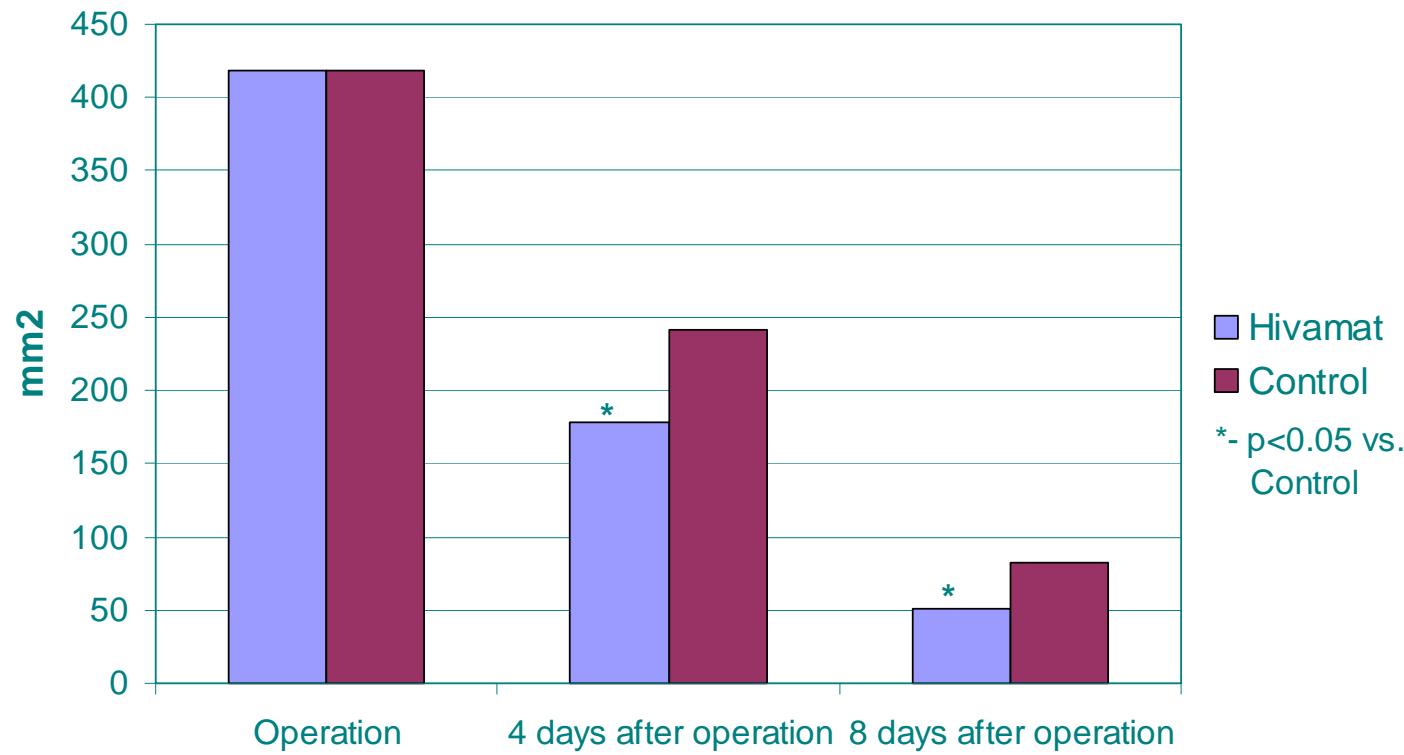
HIVAMAT



CONTROL

# Wound Healing Effect

Planimetry results



# Wound Healing Effect

*(4 days after operation)*

---



HIVAMAT



CONTROL

# Wound Healing Effect

*(8 days after operation)*

---



HIVAMAT



CONTROL

# **TACTICS OF THE SURGICAL TREATMENT OF THE PATIENTS WITH LYMPHEDEMA OF EXTREMITIES.**

*A.I. Shevela, M.S. Lyubarsky,  
O.A. Shumkov, A.V. Evorskaya,  
V.V. Nimaev, V.A. Egorov*

*The Institute of Clinical and Experimental  
Lymphology  
Novosibirsk Russia*

# **INSTITUTE OF CLINICAL AND EXPERIMENTAL LYMPHOLOGY**

**Our experience of treatment of upper  
and lower extremities lymphoedema  
allows us to propose the following  
way of surgical tactics**



- Conservative therapy
- Prophylaxis of erysipelas
- **Microlymphnode-venous anastomosis on the assumption of absence concomitant venous component of edema and inguinal lymph nodes sclerosis**

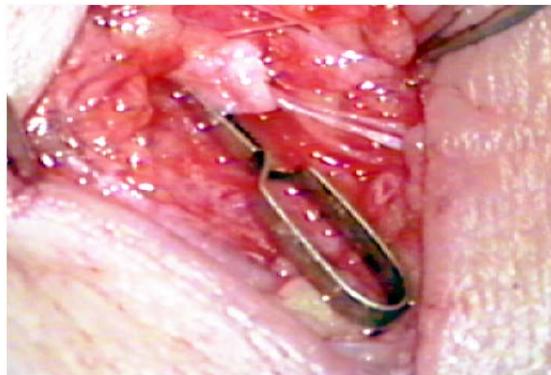
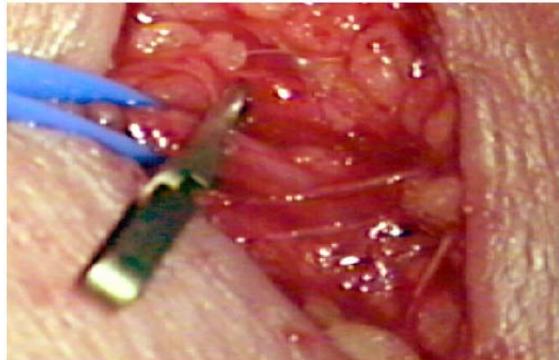
## Primary leg lymphedema (early stages)



- Prophylaxis of erysipelas
- Conservative therapy
- **Microlymph-venous anastomosis on the assumption of absence previous erysipelas**

## **Secondary leg lymphedema (early stages)**

- Prophylaxis of erysipelas
- Conservative therapy
- **Microlymph-venous anastomosis on the assumption of absence previous erysipelas**



## Postmastectomy lymphedema (early stages)



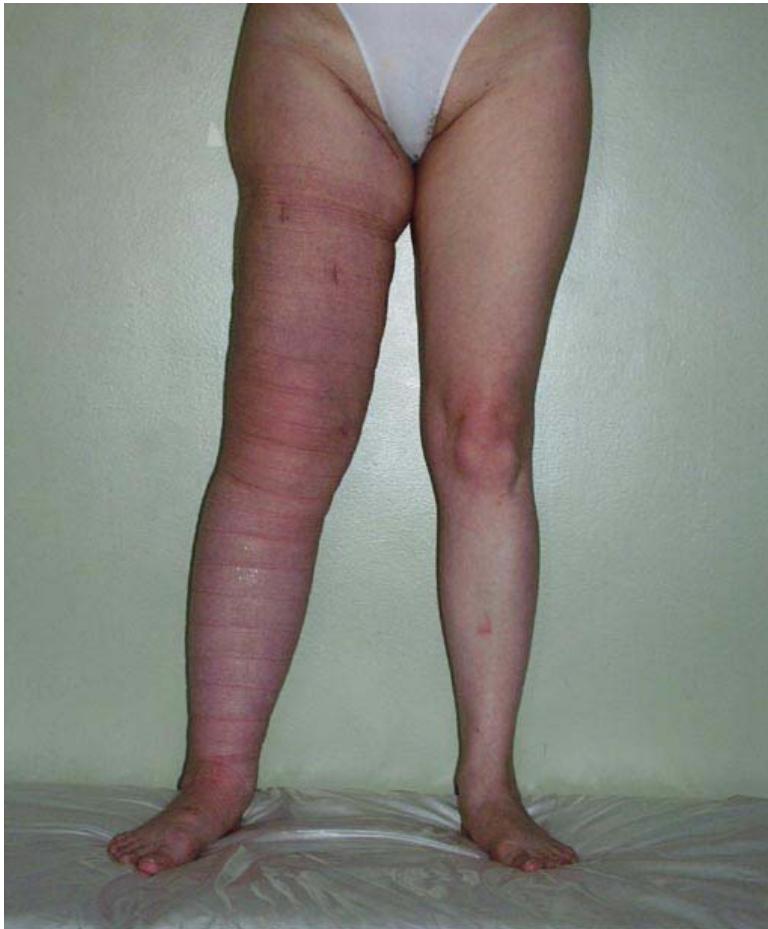
- Conservative therapy
- Lymphotropic immunomodulating therapy
- **Liposuction with endoscopic fasciotomy**

**Postmastectomy lymphedema (III stage)**



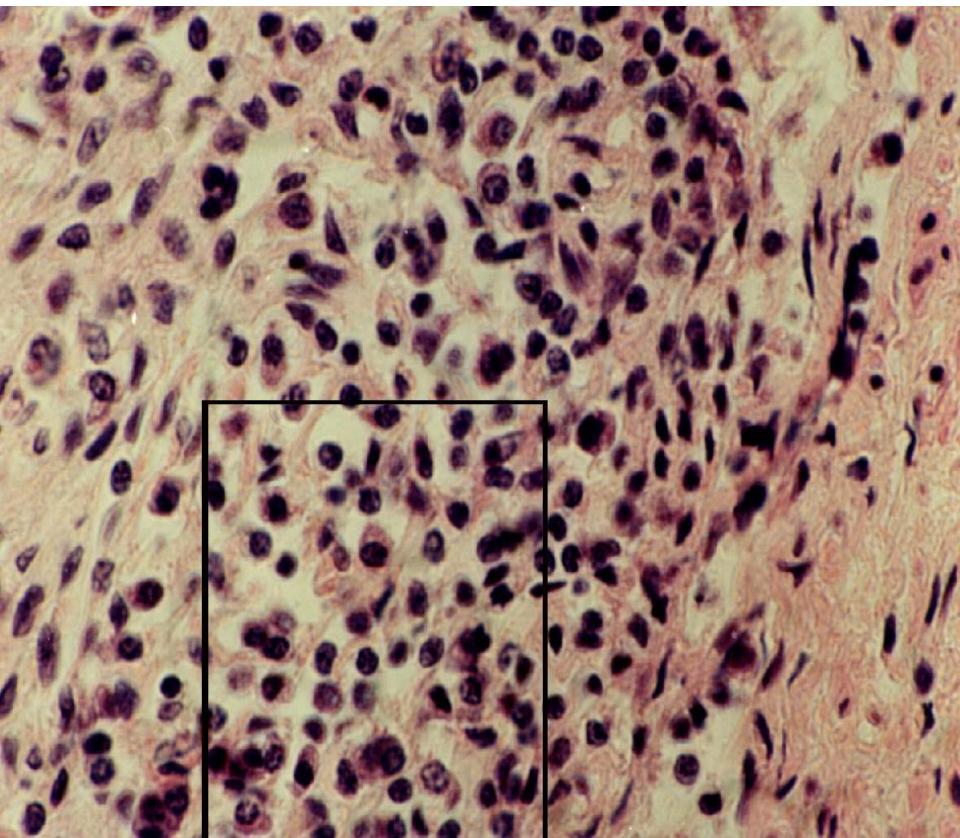
- Further check-up appeared good results in 81.5% of patients after liposuction with endoscopic fasciotomy

## Postmastectomy lymphedema (III stage)



- Further check-up appeared good results in 37.5% of patients after liposuction with endoscopic fasciotomy

**Primary leg lymphedema (III stage)**



- Basic conservative therapy
- Prophylaxis of erysipelas
- Gravitation surgery methods
- Reduction surgery

**Extremities lymphedema (IY stage)**

# Homans' procedure partial resection of lymphedematous tissues



# Homans' operation



# Charle's procedure - total resection (along the circle of the limb) of lymphedematous tissues with the primary skin-grafting



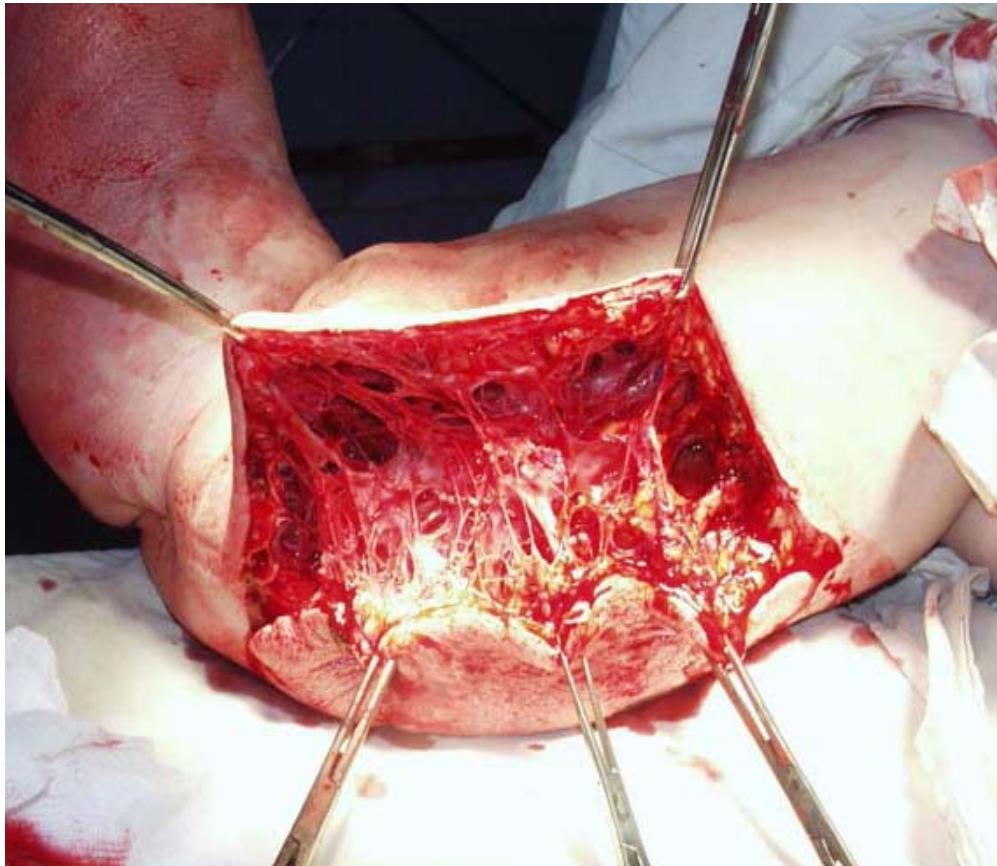
# **New application of liposuction procedure**



**Combination of  
liposuction and  
reduced  
operations**

**(Prepared stage)**

# New application of liposuction procedure



**Combination  
of liposuction  
and reduced  
operations  
(preservation of  
lymphatic  
network after  
liposuction )**

# New application of liposuction procedure



Combination of  
liposuction and  
reduced  
operations  
(Final  
appearance after  
liposuction and  
removing of skin  
flaps)

# New application of liposuction procedure

**Combination of  
liposuction and  
reduced operations  
allows to receive :**

- Reduction of operation's time
- Reduction of intra-operation bleeding
- Reduction of hospital staying

# **Tactics of Extremities Lymphedema Treatment**

- **Early complex conservative treatment**
- **Prolonged lymph-stimulation methods**

# **Additional Possibility in Low Extremities Lymphedema Treatment**

- **Electro-stimulation therapy by using  
of «LYMPHAVISION» (Physiomed  
elektromedizin)**

# **Tactics of Extremities Lymphedema Treatment**

- **Liposuction with endoscopic fasciotomy at forming steady lymphatic edema (III stage) and with the absence of good results in the II stage of the disease in the patients with postmastectomy lymphedema**
- **Reduction operations or Combination of liposuction and resection operations in the patients of IV stage of the disease**

THANK YOU  
FOR YOUR  
ATTENTION

