

Post-authorisation studies

VACUMED

FLOW REGENERATION SYSTEM



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Vacumed Therapy (LBND) for Peripheral Arterial Disease (PAD), and Leg Disease.

Peripheral arterial disease (PAD) in the legs, sometimes known as peripheral vascular disease, is caused by atheroma (fatty deposits) in the walls of the arteries leading to insufficient blood flow to the muscles and other tissues. Patients with PAD may have symptoms but can also be asymptomatic. The commonest symptom, intermittent claudication, is characterised by leg pain and weakness brought on by walking, with disappearance of the symptoms following rest. Patients with claudication can have a significantly reduced quality of life due to their restricted mobility.

Patients diagnosed as having PAD, including those who are asymptomatic, have an increased risk of mortality, myocardial infarction and stroke. Relative risks are two to three times that of age and sex matched groups without PAD. Management of PAD provides an opportunity for secondary prevention of cardiovascular events. Both lifestyle changes and therapeutic interventions to reduce risk need to be considered.

In the UK, at least 1 in 20 people over the age of 55 have some degree of PAD. It becomes more common with increasing age. In the UK PAD is more prevalent in men 1 in 20, compared to 1 in 40 women.

The natural history of intermittent claudication gives an estimated risk of limb loss of 1% per year and a required intervention rate for critical ischaemia of 6 -10% per year. In the 20-30% of patients who experience progressive deterioration, surgical treatments may include arterial grafts to remove the blockage in the peripheral arteries. Blockages tend to occur in large arteries with a high pressure, and at the bifurcation of arteries. In extreme cases (3-6%) amputation of the affected limb may be necessary.¹

Surgical treatments are expensive. In a paper examining the lack of information on the cost-effectiveness of drug treatments, Drummond & Davies from the Centre for Health Economics at York estimated that the average overall cost of treating limb ischaemia with a graft was between £6,600 and £11,000, depending on the site of the arterial blockage, while the cost of an amputation was close to £11,000²

The Study

Questionnaires were sent out to over 60 advert respondents.

The Patients to be studied were chosen after completing a questionnaire about their symptoms. One of the main stipulations was that a PAD diagnosis had been confirmed by a doctor. Some potential patients were ruled out, mainly if they suffered from a Differential Diagnosis, i.e., (Osteoarthritis, baker cyst symptomatic, calf claudication, chronic compartment syndrome, foot arthritis, foot claudication, hip arthritis, hip claudication, nerve root compression, spinal stenosis, venous claudication.)

Patients were also excluded if they suffered from any of the following:-

- Very Low Blood Pressure
- Unstable Angina
- Mobility Issues
- Large Abdominal Girth
- Metal Implants or Pace Makers
- Severe Kidney Problems

10 patients were then selected to take part in the evaluation.

The individuals chosen were screened at the Future Wellbeing Clinic. Blood Pressure, Pulse and general overall suitability were examined, clients were also asked to complete a Visual Analogue Score (VAS).

The Patients were asked to carry on with their normal routines, and not advised to carry out any lifestyle or dietary changes. They were asked to maintain their doctors' recommended drugs and guidelines.

Diary notes were to be kept in relation to variation with symptoms in their foot/ leg, such as:-

- How far could they walk at the start of the study before the pain/cramp would start?
- Change to type or position of pain, including sensitivity to heat and cold.
- The intensity and longevity of the discomfort, before they could start to walk again.

During the study they were asked to note milestones and changes in these symptoms. Changes in leg appearance were to be noted, and any alterations in their overall general wellbeing.

Pain free walking distance (PFWD)

Treatment was to be considered successful if the PFWD increased by more than 50%.

The study lasted up to 20 sessions, twice per week from January to March, (Weather very cold all of sessions.) Occasionally due to unforeseen circumstances some appointments were missed or changed.

3 Patients did not complete the study:-

- Decided it was too far to travel
- Mis-diagnosed, Nerve problem
- Blood pressure dropped too low during treatment to be deemed safe to continue.

Vacumed settings:-

	Vacuum	Atmospheric pressure return	Time	Negative Pressure	Power Level	Programme
Stage 1	6 seconds	7 seconds	1-5 minutes	-20	3	5
Stage 2	7 seconds	7 seconds	5-10 minutes	-37	7	5
Stage 3	8 seconds	7 seconds	10-27 minutes	-40	10	5
Stage 4	5 seconds	8 seconds	27-30 minutes	-44	12	5

Visual Analogue Score

10 = Severe pain, 0 = No Pain

Patient	Start	End
Vd 1	7.5	0.5
LC 2	6.5	2.5
Ph 3	5	2.5
TJ 4	7.5	2.5
LH5	7.5	2.5
DB6	5	1.25
AM7	7.5	continuing

Pain Site Severity Intensity

	START	FINISH
1	Diagnosed 2.5 years previously. Very painful legs especially when trying to walk fast. No swelling in the legs. Rest alleviated the pain	Pain is not excruciating, and can now walk through it, as it does not make him freeze up. Site has moved from ankle and calf, calf only. Feet are also warmer at night
2	Severe pain in left calf which stops him from walking. Feet are very cold at night, uses bed socks and warming bottle	Cramp is much improved. Now mainly gets it if sitting awkward. Site has changed to ankle rather than calf. Does not have to use hot warming bottle in bed at night.
3	Diagnosed in 1996 left leg, 2003 right leg. 75% blockage to the artery in right leg. Pain excruciating,	10% improvement in the walking distance before he notices pain, but intensity has lessened, he now notices the pain in his rheumatoid hip first, which he comments that he never managed to walk far enough before as had to rest due to the excruciating cramp from PAD. He also feels that the pain in his right leg, which was the worst, has recovered to the intensity of his left leg.
4	Cramps in both legs, which are so severe that he has to sit and rest quite often	Big improvement can now climb the stairs at home without the cramp starting, when it does, it is more of an ache that he can walk through.
5	Diagnosed 7 years previously. Still smokes. Pain in both calves	Intensity not as digging. Pain is not as prevalent, would be shopping before he realizes that he would normally have had pain, long before his actual pain occurs.
6	Both calves, very severe and freezes his walking	Pain now does not freeze him, and he finds that his hips will ache first. Left calf now has no pain, right calf has moved to edge only
7		

Walking Distance

Patient	START	FINISH	INCREASE
1	400 yards	1760 yards or more (mile)	340%
2	200 yards	600 yards	200%
3	50 yards	100 yards	100%
4	50 yards	300yards	500%
5	150 yards	500 yards	233%
6	440 yards	1760 yards	300%
7			

Overall Wellness

	START	FINISH
1	Suffers from PMR (Polymyalgia rheumatic)	Improved overall wellness
2	Sleeps very badly due to pain. Most nights only manages 2 hours	Feels better in himself can now sleep or up to 4 hours at a stretch before waking.
3	Generally ok	Feels more positive
4	Fed up with the restriction with his lifestyle due to the pain	Happier now that he can move around. He is now sleeping better as feet so much warmer
5	Bit depressed, eager to try anything.	Looked forward to the sessions as he always felt invigorated afterwards.
6	Basically fine, but fed up with the restrictions, the disease imposes	Feels invigorated, and planning holidays without worrying about walking.

Signs and Symptoms

	START	FINISH
1	Hair loss, varicose veins.	Fine hair growth on legs
2	Cyanosis, atrophic changes, decreased temperature	Temperature and pallor changes improved. Slight hair growth
3	Cyanosis, cold feet.	Increase in skin colour pigmentation. Ulcer scar visibly improved. Feet warmer
4	Atrophic changes, decreased temperature	Legs warmer, and increase in colour.
5	Atrophic changes, parasthesia, cold	Feet much warmer, improved skin tone, parasthesia not as noticeable
6	Atrophic changes, cold.	Feet not cold in bed any more. Wife noticed hair growth on his legs

Comments

	FINISH
1	Never expected the pain to go away totally therefore very happy with the result. Would definitely recommend the therapy to a close friend.
2	Didn't realize one morning how frosty it was outside when he woke as legs so warm. He has noticed his walking speed has improved.
3	Would carry on coming if he did not have to pay for it. Does not want to be able to run though as he would lose his disabled car sticker!
4	Looking forward to being able to mow the lawn. Has taken up cycling again. On holiday was able to walk up hills with his family. Has given up the chiropractor.
5	Feels far more relaxed as the pain is not so much a burden, therefore he feels as though he has mental health improvement
6	Not worried about going out for a walk anymore.

Conclusion

Most of the patients managed between 17 and 20 sessions.

All of them had an improvement in their Visual Analogue Scale, from 6.5 averages at the start, to an improvement of 1.95 averages at the finish.

Walking distance improvement in all patients was a minimum of 100% to a maximum of 500%, therefore exceeding the target of 50% improvement.

The overall conclusion of all patients was that they had definite improvement in their walking distance, a reduction in pain intensity, along with earlier recovery times.

Patient 7 referred by a local GP has continued with the treatment due to concomitant diseases to the PAD.

He is recovering from carcinoma of the penis, and, after surgery has used attenuated medication instead of chemotherapy. Associated with the surgery he has lymphoedema, of both legs, this aggravates the skin deterioration on both legs, and ulcer on his right leg.

Up to the tenth treatment, there was improvement in the limb size and skin deterioration. He then suffered a severe bout influenza which meant that he could not continue with the treatment for 3 weeks.

Upon return he was very frail and still suffering from a chest infection.

His leg lymphoedema was quite severe and, required diuretics. As he is following an attenuated medication program the type of diuretic he would take was quite difficult to attain.

The priority therefore upon his return was to reduce the swelling, and regain the advances made with the leg ulcer.

I therefore added to his therapy with Intermittent Pneumatic Compression Therapy (Slide Styler by Weyergans.de) at a pressure of 20mmhg for 30 minutes after massage on his lymph nodes.

Then he went into the Vacumed for 10 seconds of negative pressure of -20, then returning to atmospheric pressure for 12 seconds. This lasted for 30 minutes.

The lymphoedema has greatly reduced and the legs are continuing to recover.

His latest Doppler results are

09.10.07 Left ABPI 1.05, Right ABPI 0.89

19.2.08 Left ABPI 1.10, Right ABPI 0.83

He is also trying to detoxify his body from mercury poisoning.

10 Sessions into the study, I also started to study another patient, who has severe PAD including Toe amputations, together with the underdeveloped vascular system of a 12 year old.

He is in severe pain with a walking distance of 50 yards. The most pain apart from his legs, is from the amputated toe sites.

After his first 10 sessions he has an improvement in the PFWD, including for the first time in many years the ability to do some gardening!

Unfortunately the phantom pains are so severe that it is affecting his overall wellbeing.

Patient 1 and 6 have returned 4 weeks post end of treatment for a top up session. They state that they have had no degradation in their condition, and that the overall wellness they felt at the end of the study has maintained.

In conclusion, the use of Lower Body Negative Pressure, Vacumed, has shown to have great benefits for patients with Peripheral Vascular Disease. This is in addition to the good results shown with the treatment of cellulite, oedema, varicose and spider veins.

Vacumed therefore needs a larger study in the UK to complement the European studies that have been done.

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Dermatological application of VACUMED device for the treatment of chronic venous insufficiency for patients in stadium III-IV.

Test period: 1. September until 31. December 2001

Place of test: St. Stephan Hospital in the capital Budapest, Dermatological Department I.
(1096 Bp. Nagyvárad tér 1.)

Department Head: Dr. László, Lecturer of medical University in Budapest

Attending Doctor: Dr. Balogh György, Adjunctus

Assistent: Gágyorné Németh Éva, Nurse

Objective target: To proof that the application of the VACUMED for patients suffering from chronical venous insufficiency in the stadium III-IV reduces the volume of the interstitial lymph oedema, which is measurable in body weight and leg circumference. No changes made in the normal internal (medication) or local (dermatological) treatments were made.

Method: All patients in the test have undergone ambulant treatments. The normal internal (medication) and local (dermatological) treatments of the patients were not changed. The daily drinking quantity of mineral water was increased up to 2.000 ml for each patient. Each patient will undergo 10 treatments with the VACUMED.

The set parameter for each patient is:

Treatment time: 20 min
Vacuum power: 45 mbar
Time of neg. pressure: 6 sec
Pause (atmospheric pressure): 6 sec

Before application the following measurements of each patient was taken:

- Body weight
- Waist circumference
- Hip circumference
- Thigh circumference (left leg)
- Ankle circumference (left leg)

The 10 treatments were distributed within 30 days. After the 10th application, measurements as stated above were done again. The results were compared in total as well as per each gender with the initial measurements.

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As a control group we have chosen the same group of patients: 30 days prior to the VACUMED test we have observed all the patients.

The big difference in average age of women and men is explained by the fact that women suffer earlier from this disease than men.

Evaluation of the control group: under the usual or equal life style and alimentation, no changes in body weight nor any reduction of circumference was observed during the 30 days observation period.

We can assert that the circumference of the ankle of the men has reduced 0,5% more than the ankles of the ladies. The average reduction of 2% is a significant success due to less connective tissue and the oedema.

Summary:

The constitution of 18 patients regarding gender and age shows clearly the concern of women and the manifestation of the symptoms especially in younger age groups.

Both, men and women, reacted positively towards the application with the VACUMED. The minimal reduction of the body weight compared to the significant reduction of circumference, is a clear sign for the overlap of the liquids. The lymph oedema in the lower extremities has released and was diffused efficiently in the blood circulation.

The lymph liquid predominantly from the area of the thighs was flowing in central direction rather than from the lower part of the leg with less connective tissue. This is normal in the stadium III – IV, as most of the patients do already have open legs. At this stage of the disease the connective tissue indurations and Liposcleros is almost irreversible.

The general wellbeing, the physical capacity, the walking distances and the wound healing have improved significantly at all patients.

The treatment with the VACUMED does also have a euphoric, mental effect and eliminated the depression due to the disease. During the treatments we did not discover any contra indications. Some patients felt a slight vertigo and a slight increase of the blood pressure.

One patient has reported about gallstone cramps, another one about an aggravation of the Ein Patient hatte über Gallenstein-Krampf berichtet, wieder ein andere über die Verschlechterung der haemorrhoids.

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Due to the positive results we recommend that VACUMED should be applied in the early rehabilitation after deep vein thrombosis, were the lymph oedema of the lower extremities is still reversible. In this case the release or the movement of the lymph oedema can promote the recanalisation of the veins.

The LBNPD treatment can become an active rehabilitation and physical therapeutical application following different vein diseases such as secondary lymph oedema.

Dr. Balogh György

Test - Group:	total	18 Patients
	Women	11 Patients
	Men	7 Patients

Average age:	total	53,11 Years
	Women	47,1 Years
	Men	62,5 Years

Evaluation			<u>Before treatment</u>	<u>After 10 VACUMED treatments</u>	<u>Difference</u>	
					in %	absolute
Weight	Total in kg:	Women	820,0	816,0	-0,5%	-4,0
		Men	647,0	644,5	-0,4%	-2,5
		total	1.467,0	1.460,5	-0,4%	-6,5
	Average in kg:	Women	74,5	74,2	-0,5%	-0,3
		Men	92,4	92,1	-0,4%	-0,3
		total	81,5	81,2	-0,5%	-0,3
Waist circumference	Total in cm:	Women	926,0	910,0	-1,7%	-16,0
		Men	725,0	708,0	-2,3%	-17,0
		total	1.651,0	1.618,0	-2,0%	-33,0
	Average in cm:	Women	84,2	82,7	-1,7%	-1,5
		Men	103,6	101,1	-2,3%	-2,5
		total	91,7	89,9	-2,0%	-1,8
Hip circumference	Total in cm:	Women	1.150,0	1.110,5	-3,4%	-39,5
		Men	721,0	717,5	-0,5%	-3,5
		total	1.871,0	1.828,0	-2,3%	-43,0
	Average in cm:	Women	104,5	100,9	-3,4%	-3,6
		Men	103,0	102,5	-0,5%	-0,5
		total	104,0	101,6	-2,3%	-2,4
Thigh circumference, left:	Total in cm:	Women	666,0	620,5	-6,8%	-45,5
		Men	357,0	354,5	-0,7%	-2,5
		total	1.023,0	975,0	-4,7%	-48,0
	Average in cm:	Women	60,5	56,4	-6,8%	-4,1
		Men	51,0	50,6	-0,7%	-0,4
		total	56,8	54,2	-4,7%	-2,6
Ankle circumference, left:	Total in cm:	Women	256,0	251,0	-2,0%	-5,0
		Men	166,0	162,0	-2,4%	-4,0
		total	422,0	413,0	-2,1%	-9,0
	Average in cm:	Women	23,3	22,8	-2,0%	-0,5
		Men	23,7	23,4	-1,3%	-0,3
		total	23,4	23,0	-2,1%	-0,4

Prospective study of clinical effectiveness of intermittend low pressure treatment in patients with chronic arterial disease (CAD) in the lower limbs grade 2

Introduction: The intermittend low presure treatment (Vacumed®) has been developed from the LBNPD-technology (Lower Body Negative Pressure Device) of NASA (1). Angiological examinations (2,3) showed in patients with CAD an improvement of the pulswave at the toes and an increase of transcutan measured oxygenpressure during the low pressure treatment. To examine the clinical effectiveness of this treatment we did a prospective study (1.Aug 04 - 31. March 05) with patients with stable CAD grade 2: calf pain caused by walking exercise, no wounds, no pain in rest.

Question: Can intermittend low pressure treatment influence the walking distance in CAD grade 2?

Design: After clinical examination we measured in all patients of hospital fallingbostel the ankle-brachial-index (ABI). We included patients with an ABI below 0.9 and typical calf pain only during walking exercise. Excluded were patients with exercise pain due to other diseases (gonarthrosis, radicular pain). After this examination we treated at least with 10 low pressure sesssions (2-3 per week). Every session last 20 minutes, 5 seconds - 50 mbar, than 10 seconds normal pressure. We told the patient to do exercise immediately after treatment for half an hour. After 10 sessions we did a clinical examination and asked the patient, if there is some change of painfree walking distance. We gave all patients the opportunity to do more sessions, some agreed..

Findings: 23 patients CAD grade 2 (painfree walking distance 30 - 500 meter) were included. The ratio man:woman was 2:1, average age 75 (61-82) years, the CAD apparent 2 - 20 years. The patients reported no problems during treatment. 4 patients noticed no change of painfree walking distance, 19 patients noticed an improvement. The average of improvement was 72% (30 - 130%). The 23 patients received 14 (10 - 30) sessions in 5 (3 - 12) weeks.

Discussion: The improvement of CAD induced by exercise is well examined (4,5). In 6 months patients reach an improvement of around 150% of their painfree walking distance (6). In shorter treatment-periods the improvement is smaller. We found in 2003, treating 45 patients three weeks with walking exercise and gymnastic, an average improvement of 40%. With intermittend low pressure treatment we found an improvement of 72% in a treatment time of 5 weeks. This is surprising, because the patients did not do intense walking exercise or gymnastic every day - only walking exercise after low pressure session 2 or 3 times a week. All patients reported the treatment as pleasant and that walking is somehow easier after the low pressure session.

Result: With the intermittend low pressure device (Vacumed®) and walking exercise immediately after treatment we induced in 19 of 23 (83%) patients with CAD grade 2 an improvement of the painfree walking distance. We didn't see a deterioration. This effect is stronger than the improvement caused by walking exercise and gymnastic. To gather more understanding of this method (dose-effect-relation) and of clinical implications further studies are needed, as Diehm already recommended (7).

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Assessment of the benefits of Vacumed in wound healing.

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The Vacumed was made available to the Eastbourne Wound Healing Centre for one week. During that time, 5 patients took part in an evaluation of the benefits to healing. The diagnosis of each patient was different:

- Arterial disease (2 patients)
- Mixed aetiology (venous and arterial)
- Pyoderma Gangrenosum
- Sinus wound in the hip

Each patient was placed in the machine on a level of 30 and each patient was monitored every 5 minutes for oxygen saturation levels.

The outcomes suggested that people with arterial disease had oxygen levels that increased from the lowest of 84% to between 97% and 98%. Those patients with no arterial disease had decreasing saturation levels from an average of 98% to 91%.

Four Patients improved during the treatment. The patient with Pyoderma Gangrenosum did not do well but this was thought to be a problem due to a spike in her disease rather than the treatment. The patients with arterial disease progressed to a healing status faster than those with venous disease. His pain levels dropped from 10 to 0 and remained at 0 for 4 weeks post trial.

The patient with a sinus found that levels of exudate increased during treatment, and this was thought to

Eastbourne Wound Healing Centre surmises that the patients with arterial disease had improved oxygen saturations because their disease ensured the blood supply was poor and the Vacumed reversed that situation. Whereas, those patients with venous disease have too good a blood supply which cannot reach the tissues effectively because of the nature of the disease and the negative pressure actually increases that problem by bringing even more blood into the peripheries. If the treatment differed for each patient i.e: those with arterial disease have the negative pressure as described, but those with venous disease had the cellulite treatment, (reversing the blood flow) then the Vacumed would undoubtedly be more effective.

Conclusion.

The Vacumed has treatment for cellulite and this reverses the flow and would be very useful for patients with venous disease. Arterial disease almost certainly will improve with Vacumed.

The outcome of this small assessment has led the Eastbourne Wound Healing Centre to investigate the potential for purchase of a Vacumed for patients with difficult to heal leg ulcers.

Case study Assessment of the benefits of Vacumed in wound healing.

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Mr T is a 71 year old gentleman who as had arterial disease since he was 45 years old. The skin of his right leg had broken down and remained unhealed for 5 years. Doppler assessment could not identify any pulses in the right leg and the skin was pale and grey. He constantly suffered nerve pain which at night could be 'excruciating'.

Two weeks prior to Vacumed, he saw the vascular consultant who told Mr T that he would have to consider an amputation and arranged to see him 4 weeks later to hear Mr T's decision.

He was placed in the Vacumed for 30 minutes daily for 8 days. His Oxygen saturation levels were monitored every 5 minutes to identify whether the microcirculation could be improved.

Mr T's average oxygen saturation level at the start of the treatment was 92% and at the end of each treatment was 100%. During the eight days, his pain levels reduced from 10 (excruciating) down to 0 (no pain) and it remained at this level for 4 weeks post treatment.

During and following treatment, his wounds improved and his skin became pink. He was able to commence physiotherapy and his quality of life improved greatly.

One week post treatment, he saw the vascular consultant. He was extremely pleased with the state of Mr T's wounds. He felt they had improved and that the skin had a healthy appearance. He did not wish to undertake the amputation and discharged Mr T without a follow up appointment.

Unfortunately, the treatment benefits are now beginning to wear off, Mr T cannot access the Vacumed and the skin on his right leg has deteriorated again.

TRANSLATION

Vacumed

Intermittent negative pressure therapy
Weyergans AG

Report about the Vacumed for a treatment observation in the clinic from

Dr. Streminski

and colleagues, Richard – Wagner Street 9-11, 50674 Cologne
Period from March 01 till July 01

The datamaterial from this study results from 10 test- patients
It is a question of patients with AOD in the stage of 2 and clinical diagnostic of periphery micro circulation disturbance in the feet.

Before treated with Vacumed, a well grounded anamnesis was done.

Success Indication was tested with following equipment:

- Increase (Akrale) pulse – measuring on the toe
- LLR periquant 815, Company Dr. Ing. J. Gutmann (Eurasburg)
- Trans- cutaneously
- Company Radiometer GmbH (Copenhagen)
-

Performance:

A treatment time of 20 minutes with 40-50 mm Hg negative pressure.
Altogether they took 6 treatments per patient every 2-4 days

Summary:

The measurements were done exactly before the treatments starts, during the treatments and 30 minutes after the treatments.

Average increase from O2 mm Hg compared to a reference - value before treatment:

During treatment:	+14%
After treatment (30 min.)	+ 8%

The increased (Akrale) pulsation with elevation of the negative pressure was clearly higher .

Result:

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This equipment is after the summary of the treatment-observations indicated for periphery micro-circulation disturbance, p. example for diabetics, Angiopathie, Ranaud or Thrombangitis obliterans.

The indication for AOD is near at the hand because of the results, but it must be tested on a bigger patient group for a longer period.

The therapy is even interesting for the above shown indications, especially in connection with simultaneous oxygen therapy – and /or infusion therapy.

7 from 10 patients told about a subjectiveness recovery from the problematic of the bodily complaints.