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Use of devices for intermittent negative pressure therapy for treatment of athletes

Key Words: Intermittent Vacuum Therapy, IVT, lower body negative pressure device, LBNPD, Rehabilitation acceleration, Vacusport, Vacumed.

Abstract

Intermittent vacuum therapy -IVT- was developed by NASA on the basis of the LBNPD procedure (lower body negative pressure device). This kind of therapy is used to treat vascular diseases of the legs, to accelerate rehabilitation of athletes, to reduce oedema in the lower extremities, to treat cellulite as well as other indications.

At the N. N. Priorov Central Institute for Traumatology and Orthopaedy, department of sports and ballet injuries³, 30 patients, all professional athletes, were treated by means of the Vacusport device with intermittent vacuum therapy following arthroscopic meniscus resection and stabilizing interventions on the front and rear knee joints.

All patients recovered well after the treatment. In comparison with a control group, faster reduction of oedema, reduced sensitivity to pain during physiotherapy and accelerated resorption of exusdates according to statements of ultrasound examinations were observed.

Introduction

Intermittent vacuum therapy was developed by NASA on the basis of the LBNPD procedure (lower body negative pressure device) (http://nssdc.gsfc.nasa.gov/nmc/experimentDisplay.do?id=1973-027A-51). After space flights, orthostatic tolerance of astronauts is re-established by means of the LBNPD procedure in combination with exercises (Watenpaugh DE et al., 2007). The LBNPD procedure may also have positive effects on the recovery of the baroreceptor reflex and the venous tone in the lower body during space flights (Fortney SM, 1991). In combination with medication treatment, the LBNPD procedure is used for therapy of orthostatic hypotension of astronauts (Lathers CM et al., 1994).

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Structure of the Device

The device for intermittent vacuum therapy consists of a cylindrical chamber into which the lower body of a patient is placed. The patient is lying on his back, his legs and lower body up to the crest of the iliac bone are inside the chamber. In the area of the waist, the chamber enclosing the lower body of the patient is sealed by means of a diaphragm. A vacuum pump generates negative pressure in the chamber. The device generates intermittently negative and normal pressure.

Under the effect of the vacuum, blood from the area with relative high pressure (upper body outside the chamber) flows into the area of lower pressure (lower body inside the chamber), thus improving blood circulation in the lower extremities. Due to the blood flow towards the lower extremities, the mean blood pressure falls. Normally, the body compensates for the redistribution of blood by increasing the pulse rate and peripheral vascular constriction. Due to the blood flow towards the lower extremities, the mean blood pressure falls (Repetition in the original; translator’s remark). (http://nssdc.gsfc.nasa.gov/nmc/experimentDisplay.do? id=1973-027A-51; Esch BT et al., 2007).

Physiological Principles

The negative pressure in the lower body is used in order to model gravity and bleeding, to change initial tension and effect on baro-receptors as well as to examine patients with cardiac insufficiency, athletes, astronauts and elderly people (Esch BT et al., 2007).

Using negative pressure in the lower body makes it possible to control venous reflux and thus model-controlled hypovolemia (Nette RW et al., 2003).

Low pressure in the lower body is used to simulate exsanguinations and to model orthostatic stress because several changes of neuro-vascular physiology are similar for upright and bent body positions. Both relief the cardio-pulmonary and arterial baro-receptors to a certain degree. However, there are differences in local events in blood vessels. In contrast to a bent body position, visceral vessels are obliterated as a result of intermittent vacuum therapy. Vessels are obliterated in proportion to the negative pressure; venous constriction is supported (Taneja I et al., 2007).

Due to the negative pressure in the chamber, the negative pressure in the lower body triggers the movement of the circulating blood volume into lower extremities and abdomen. This blood movement results in lowering the blood pressure in the central vein, heart beat volume, cardiac output and, finally, in lowering the arterial blood pressure, which must be met by compensation mechanisms. All in all, the short-term reaction is a changed total resistance of blood stream, venous tone, frequency and width of heart contractions (Kappel F et al., 2007; Hisdal J et al., 2001).

The cardiovascular system reacts to the reduced heart beat volume and blood pressure in the central vein by increasing the pulse and the peripheral vessel resistance. This reaction includes re-
duction of the parasympathetic effect on the heart, activation of the sympathetic response to the heart and the peripheral vessels, increase of the catecholamine secretion, of the plasmarenin activity and reduction of the release of the atrial natriuretic peptide (Gasiorewksa A et al., 2006).

Directly proportional to the effective negative pressure in the lower body, the amounts of deoxygenized and overall haemoglobin in the muscles of the lower extremities are increased. The amount of oxygenized haemoglobin is increased considerably at -10 mmHg, and the curve of the amount of oxygenized haemoglobin in relation to the effective negative pressure becomes constant when the pressure is increased further. The increased amount of deoxygenized and of overall haemoglobin may be an indication for blood retention in the venous system and adjustment of the blood volume to the changed pressure in the lower body. On the other hand, the changed oxygenized haemoglobin reflects the collection of blood in the arterial system of the correlation of mechanical extension and sympathetic vascular constriction caused by the negative pressure (Hachiya T et al., 2004).

For healthy volunteers, negative pressure in the lower body results in lower blood pressure in the central vein starting from a negative pressure of -20 mmHg, while higher values cause a decreased heart beat volume and cardiac indicators (Nette RW et al., 2003).

It is generally assumed that the negative pressure in the lower body up to a value of – 20 mmHg does not change the mean blood pressure (Hisdal J et al., 2001). Due to the increase of the overall peripheral resistance and the pulse, the arterial blood pressure usually remains unchanged; however, at a negative pressure of -40 mmHg and less, hypotension may develop. In case of healthy volunteers, the hypotension risk increased with hypovolemia (Nette RW et al., 2003). Other information indicates that the systolic blood pressure at a negative pressure of -50 mmHg decreases moderately, although the mean blood pressure and the diastolic blood pressure at various values of the negative pressure in the lower body remain at a certain level (Hachiya T et al., 2004).

In case of healthy volunteers, the pulse rate increases when applying negative pressure within 5 minutes at -50 mmHg and in the model of orthostatic instability at a negative pressure of -30 mmHg (Lathers CM et al., 1994).

When examining the tolerance for negative pressure in the lower body it was observed that younger and more athletic men and women have a more adequate venous tone; however, the tolerance of the maximum negative pressure in the lower body does not depend on this (Hernandez JP et al., 2004).

Although in there are sex differences in the adrenergetic response, which may play a role with regard to the tolerance of intermittent vacuum therapy - and it is assumed that women have a lower orthostatic tolerance – no differences between men and women were discovered in the examinations when the blood pressure in the central vein or the cardio-vascular system and baroreceptor reaction was changed (Franke WD et al., 2003).

Physiological examinations determined that patients with diabetes type 2 show symptomatic dysfunction, however with cerebral self-regulation, which shows during intermittent vacuum therapy in lowered arterial blood pressure and in the speed of blood circulation in the brain with accompanying increased pulse rate, although transport function and phase displacement remain stable (Marthol H et al., 2007).

The body condition responds in two ways to orthostatic tolerance. Orthostatic tolerance is the ability to maintain the blood flow in the brain when the body position is changed. It is assumed that the mechanisms to maintain the blood flow in the brain correlate with age and body condition (Hernandez JP et al., 2005).
It is known that orthostatic tolerance is disrupted for persons who exercise intensively as well as for patients who are bed-ridden. Athletes with high endurance tend to have low orthostatic tolerance. When modelling orthostatism in the laboratory, athletes with high endurance have a more distinct reduction of the heart beat volume than untrained persons. Intensive endurance exercises may reduce orthostatic tolerance by re-modelling the myocardium and by a steeper volume-pressure curve. This results in an excessive reduction of the heart beat volume in upright body position. Other mechanisms contributing to frequently occurring orthostatic intolerance of athletes include increased sensitivity of the carotid baro-receptors and reduced vascular reactivity to sympathetic stimulation as well as change of the vein tone in the lower extremities.

The latter factor is the least significant. It was also demonstrated in orthostatic tests that athletic persons have a higher filtration of the calf capillaries in a bent body position. This mechanism may play a role in case of intolerance against heavy weight stimuli. On the other hand, some information indicates that aerobic stress is not related to orthostatic intolerance, and that long-distance runners have a higher orthostatic tolerance than untrained persons. Generally, for most people moderate exercises do not interfere with orthostatic tolerance, and for some people they increase a low tolerance (Gasiorowska A et al., 2006; Nazar K et al., 2006).

Since it was shown that venous backflow into the lower extremities in case of negative pressure in the lower body is more significant than for backflow into the abdomen it is assumed that for persons with higher venous resilience in the lower extremities negative pressure in the lower body causes a higher blood reflux and therefore lower tolerance against intermittent vacuum therapy.

Muscles rather than fat or bones prevent blood depots in the lower extremities. As a result, when muscular mass in the lower extremities is lost (e.g. in case a patient is bed-ridden) the venous resilience in the lower extremities is increased. Therefore, muscle-building exercises are bound to increase tolerance against intermittent vacuum therapy (Lawler LA et al., 1998).

It is known that in the course of ageing the affinity to orthostatic hypotension increases, which may increase the risk of falling for such persons. In a continuous examination it was established that endurance training over six months increases the venous tone for elderly people while not reducing the tolerance against intermittent vacuum therapy (Hernandez JP et al., 2005).

However, in a different continuous examination it was stated that neither age nor condition has any effect on the tolerance to orthostatic stress modelled with negative pressure in the lower body. Although depending on age and condition, differences are observed in terms of the response to sub-maximum orthostatic stress; these differences are not correlated to the tolerance differences (Hernandez JP et al., 2005).

Tolerance to intermittent vacuum therapy increases after repeated treatments, which is achieved by increased ability to contract of the heart ventricle, lowered resilience of the peripheral vessels, adjustment of the reflex mechanism to hypotension correction and increased blood pressure (Yang CB et al., 2000).

The majority of the examinations of physiological effects of intermittent vacuum therapy is based on reactions to stable negative pressure in the lower body. When adjusting the negative pressure in the lower body and returning to normal pressure, transition effects can be observed, such as lowering of the mean blood pressure when negative pressure is applied (Hisdal J et al., 2002).

When a negative pressure of -20 mmHg is quickly reached and the return to normal pressure also happens quickly, change of pulse, mean blood pressure and heart beat volume are observed. The response of the cardio-vascular system is asymmetrical, especially with regard to the heart beat volume. When applying negative pressure, the heart beat volume decreases slowly within 50 sec;
return to normal pressure causes a fast return of the heartbeat volume to the original level within less than 10 sec. The neutral response causing the overall vessel resistance is not sufficient to compensate for a fast change of the negative pressure in the lower body. The change of the mean blood pressure is caused by the fact that apart from low pressure baro-receptors also arterial baro-receptors are activated, which react to the mean blood pressure in the event of fast reaching and discarding of low negative pressure in the lower body (Hisdal J et al., 2001).

Changes of the haemo-dynamic values to the level of the macro-organism have to be accompanied with perfusion changes on tissue level. In this regard, NASA and DLR (German Centre for Aviation and Space Travel) have stated that application of treatment devices for intermittent vacuum therapy (Vacumed and Vacusport by Weyergans High Care AG) causes drastic capillary dilatation and capillarization with simultaneous increase of the micro- and macro-perfusion in the lower extremities (Lathers CM et al., 1994).

Such devices are called “external heart for the lower body”. Unlike the devices used in space medicine, Vacustyler, Vacumed and Vacusport operate with intermittent negative pressure and defined intervals. The alteration of negative and normal pressure increases capillarization and capillary dilatation and increases the flow of oxygenized blood in the lower extremities. During the phase of normal pressure, venous blood and lymph move into the larger vessels (increased backflow). The accelerated micro-perfusion and lymphatic drainage result in a pH increase. This can be used to strengthen the connective tissue (increase collagen synthesis) and for cellulite treatment which is related to disrupted lymphatic drainage according to current scientific opinion. Since different treatment methods promote different reflexes during intermittent vacuum therapy that can be used to trigger various specific responses (Goswami N et al., 2008), an extension of the negative pressure phases is used to stimulate arterial perfusion; an extension of the normal pressure stages is used to increase backflow of venous blood and lymph (http://www.vtstyrler.co.uk/Vacustyler2.htm).

**Effects in Case of Pathology**

Similar to the use for astronauts after space travel, devices for intermittent vacuum therapy have been successfully used against orthostatic instability of bedridden patients (Lathers CM et al., 1993).

Angiological examinations with patients suffering from chronic arterial diseases have proven an improvement of the pulse wave in the toes and an increase of the oxygen particle pressure measured through the skin after intermittent negative pressure therapy (Straminski et al., 2001; Strauss, 2001).

The effectiveness of treatment with Vacumed was examined on patients suffering from arterial obstruction stage 3 and 4 according to Fontaine. The effectiveness of the treatment was evaluated
by means of measuring the pulse wave in the toes with LLR Periquant 815 (Gutman) and oxygen pressure measurement through the skin (Radiometer G mbH). The therapy included 6 treatments of 20 minutes each with intermittent negative pressure of -50 mmHg. A significantly increased pulse wave and oxygen particle pressure in the toes directly after the negative pressure treatment is proven (Strauss, 2001).

Straminski et al. (2001) examined the effectiveness of intermittent vacuum therapy with Vacumed on 10 patients suffering from arterial obstruction of stage 2 in the lower extremities and with clinically diagnosed disruption of peripheral micro-circulation in the feet. The therapy included 6 treatments of 20 minutes each with negative pressure of -40 to 50 mmHg with intervals of two to four days. The pulse wave and the oxygen particle pressure in the toes was measured immediately before the treatment, during the treatment and 30 minutes after the treatment. The oxygen particle pressure was increased by 14% during the treatment and 30 minutes after the treatment it was 8% higher than before the treatment. During the treatment, increased peripheral pulsation was observed. Seven of ten patients reported a subjective improvement and less discomfort.

A similar examination with the Vacustyler was conducted on patients with disruptions of venous and arterial blood flow. Statements of 23 patients with disruptions of venous and arterial blood flow (atherosclerosis, obstruction of the thigh, knee joint, shin artery, constriction of the hip artery, coronary insufficiency, arterial hypertension, diabetes, gangrene of the foot, gangrene of the toe, critical ischemia of the lower extremities, tropical abscess of the toes, aneurism of the abdominal aorta, amputation of the lower extremities) were recorded. Three patients suffered from severe pain when walking. With accompanying medication treatment, the patients were treated with intermittent vacuum therapy by means of Vacustyler for 5 days with 2 sessions each day and another 10 days with 1 session each day. Normally, the first two treatments take 20 minutes each at a negative pressure of -25 mmHg; then the treatment was for 35 minutes at a negative pressure of -30 mmHg. All patients recovered well after the treatment; they reported decreased pain and were able to walk without problems (Solveiga A., 2003).

To evaluate the clinical effectiveness of intermittent vacuum therapy, Doctor Schink (2005) conducted an examination with patients suffering from stable chronic arterial diseases of stage 2. The objective of the examination was to evaluate the effect of intermittent vacuum therapy with chronic arterial diseases of stage 2 on walking distance. The control group included patients with chronic arterial disease stage 2, which were treated with special exercises.

The effect of the special exercises with chronic arterial disease had been examined in previous examinations; the patients were able to increase the distance of pain-free walking by up to 150% after 6 months of treatment (Gardner AW et al., 1995; Degischer S et al., 2002; Diehm et al., 2003). Doctor Schink et al. (2003) stated after examining 45 patients that walking exercises and gymnastics result in an average improvement by 40% within three weeks.

The examined group included 23 patients aged 61 – 82 years (average 75 years) with medical histories of 2 – 20 years. After a clinical examination, the patients underwent at least 10 treatments (2 – 3 treatments per week) of vacuum therapy. Each treatment took 20 minutes: Alternating 5 sec. -50 mbar and 10 sec. normal pressure.

The patients also carried out the normal exercises immediately within 30 minutes after the treatment. After 10 treatments another clinical examination and interview was conducted. All patients recovered well after the therapy and all described the treatments as “pleasant”. Four patients did not feel any change in the distance of pain-free walking, 19 patients observed an increased distance. The average increase of the distance of pain-free walking was 72% (30-130%). 23 patients received an average of 14 (10-30) treatments within an average of 5 (3-12) weeks (Schink,
2005). However, further examinations are necessary to proof the effectiveness of the treatment (Schink, 2005; Diehm et al., 2003).

At the institute Euromedicine Biophyderm (Montpellier, France) a clinical examination was conducted with 18 women aged 18 to 55 years suffering from cellulite problems. Each patient underwent a total of 15 treatments of 30 minutes each and 2 treatments per week with Vacustyler. Apart from the subjective results (reduction of the venous net, reduction of orange skin, of skin dryness, improvement of skin tone, strengthening of the epidermis), a considerable, even reduction of the circumference of the thigh by several centimetres was stated. All patients recovered well after the treatment (Agopian-Simoneau L, 2003).

There are also examinations of clinical application of intermittent vacuum therapy for patients with chronic cardiac insufficiency (Wolthuis RA et a., 1974).

Effects on Athletes

The effect of manual massage or lymphatic drainage during rehabilitation of athletes is well known. In this method, venous backflow is stimulated and circulation of arterial and venous blood is increased, which results in increased venous backflow and cardiac output. In addition, muscle tone and concentration of endorphins in the brain is increased.

The effectiveness of intermittent negative pressure therapy was examined during the rehabilitation of 50 professional athletes (canoeists, swimmers, rowers, footballers, tennis players and track-and-field athletes). Within 12 weeks, the athletes underwent training following their specific programmes. Half of these athletes received a 30-minute treatment of intermittent negative pressure by Vacumed every two days (-40 to -50 mbar, duration of the phases of normal/negative pressure: 7/5 sec). Simultaneously, all athletes participated in rehabilitation programmes developed by their trainers. The blood of all athletes was examined twice per week before and after training. At the beginning and at the end of the examination, all athletes underwent an extensive stress test. Before every training, all athletes were interviewed.

A total of 1,200 blood examinations were conducted, which proof for the examined group (1.48mmol/l) in comparison with the control group (1.59 mmol/l) in the resting phase before the training. The examined athletes produced a smaller concentration of urea and uric acid (40 and 3.9 mg/dl compared to 43 and 4.85 mg/dl for the control group); also, a lowered creatine kinase was found (262 U/l compared to 284 U/l). According to the results of the survey, the athletes treated with intermittent negative pressure therapy were more motivated in their exercises in comparison to the control group; they also had a better muscle tone and an overall better rehabilitation (Alf DF, 2007).

Clinical Experience of the Central Institute for Traumatology and Orthopaedy

At the N. N. Priorov Central Institute for Traumatology and Orthopaedy, department of sports and ballet injuries, 30 patients, all professional athletes, were treated by means of the Vacusport device following arthroscopic meniscus resection and stabilizing interventions on the front and rear knee joints after intermittent vacuum therapy. Control group 30 similar patients who received the traditional treatment without intermittent negative pressure. Start at the earliest seven days after the surgery and after removal of the sutures.

Indications were: An oedema after operation, pain and fluid in the knee joint. Counter indications were: Infections, chronic diseases in the exacerbation phase, vascular thrombosis of the lower extremities. To avoid thrombo-embolic complications, all patients underwent mandatory
examination of the vessels of the lower extremities by ultrasound Doppler-graphy. The existing Vacusport device allowed the generation of negative pressure intervals of 6 up to 12 seconds with normal pressure intervals of 5 up to 10 seconds at a negative pressure of -30 up to -60 mbar, adjustable in 5 mbar increments, according to the saved programmes.

*Picture. 3. Control panel of the device for intermittent negative pressure therapy.*

Intermittent vacuum therapy was used daily in at least 10 treatments of 30 minutes each according to the following schedule:

- 1st – 6th minute: 35 mbar / 8 sec. negative pressure / 10 sec. pause
- 7th -12th minute: 45 mbar / 10 sec. negative pressure / 8 sec. pause
- 13th -18th minute: 55 mbar / 8 sec. negative pressure / 10 sec. pause
- 19th - 24th minute: 60 mbar / 10 sec. negative pressure / 8 sec. pause
- 25th - 30th minute: 50 mbar / 8 sec. negative pressure / 8 sec. pause

*Picture 3. Control panel of the device for intermittent negative pressure therapy.*

All patients recovered well after the treatments and felt pleasant sensations in their legs after the third treatment. In comparison with the control group, who did not receive intermittent vacuum therapy, the examined patients showed a faster reduction of the oedema by 2 – 6 days (average 3.5) and reported less pain during physiotherapy. The check-up ultrasound examinations of the surgically treated knee joints of the examined patients established the accelerated reduction of the exudates.

As a reason for this type of therapy, we see a strong physiological effect of intermittent vacuum treatment on lymphatic drainage and venous reflux, which accelerates reduction of oedema and minimizes the pain syndrome, as well as on the resorption of exudates in the knee joint. This prevents venous backup for athletes, who often tend to orthostatic intolerance and develop disruption of the venous tone in the lower extremities that develop after an accident and during therapy.

**Summary**

The devices for negative pressure therapy of the lower extremities are an efficient tool to control blood flow in the lower extremities. This technology developed for astronauts has a clearly positive effect on adaptive blood flow forming in zero gravity. On the basis of this methodology,
models for redistribution of blood flow in the body were developed, at the same time several physiological local and system effects of negative pressure in the lower body were analyzed and undesired phenomena, counter indications and tolerance limits were determined. Up to now, no side effects were observed. The devices for intermittent vacuum therapy have a wide range of modulation options. However, intermittent vacuum therapy is only gradually used in clinics due to lacking comprehensive clinical examinations of the therapeutic effectiveness.

In addition, adequate examinations of intermittent vacuum therapy in sports medicine with regard to performance and rehabilitation of athletes are still not available. There is a great potential for modification of the therapy programmes recommended by the manufacturer. Since up to now, after 40 years in the history of the devices for negative pressure therapy in the lower extremities, no side effects were observed, the use of the devices for intermittent negative pressure therapy does not violate the main medical principle “Do not cause harm”. In addition, since intermittent negative pressure therapy has very strong and well examined physiological effects, its controlled use in clinics may bring about clear positive clinical results. Therefore, the authors find reason to promote a wide application of intermittent negative pressure therapy for various pathologies and for athletes in various combinations with other types of treatment, as well as to conduct further examination of its effectiveness and development of the treatment programmes.

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