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### 6.4 Appraisal

| **Reference No.** | 66 |
|---|---|
| **Bibliographic Data** | Campisi CC, Ryn M, Campisi CS, Di Summa P, Boccardo F, Campisi C. INTERMITTENT NEGATIVE PRESSURE THERAPY IN THE COMBINED TREATMENT OF PERIPHERAL LYMPHEDEMA. Lymphology. 2015 Dec;48(4):197-204. PMID: 27164765. |
| **Quality of evidence** | 2a |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Fifty patients with primary or secondary lymphedema received Intermittent Vacuum Therapy (IVT) with the VACUMED device in conjunction with microsurgical CLyFT (Complet Lymphaedema Functional Treatment). Twelve applications of 20 minutes each were conducted in the two weeks before surgery and an average of fourteen applications in two to three weeks immediately after surgery. Technical parameters were -35 mmHg (peak -40 mmHg) in cycles of 21 seconds of negative pressure and seven seconds of atmospheric pressure. The results were measured by water volumetry. There was a reduction in lymphedema of 83.02% (+- 10.78%), while the control group achieved a reduction of 76.44% +/- 13.48%. The administration of IVT in conjunction with CLyFT leads to 7 % more volume reduction. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | VACUMED reduces and increases both microcirculation and venous and lymphatic return. The technique is easy to apply and comfortable for the patient. In elderly patients or patients with combined lipoedema and lymphedema and fragile skin conditions, IVT is applicable and thus superior to copmpression therapy (mechanical drainage). |
| **Conclusions** | VACUMED can be used post-operatively and improves both microperfusion and venous and lymphatic return in the lower extremities. |
| **Limitations** | N/A |
| **Summary** | In an observational study of 50 patients with pronounced lymphedema or combined lymphedema/lipedema treated by vascular surgery, VACUMED was shown to reduce edema by an additional 7% compared to the control group (historical collective). Treatment duration was 20 minutes per session with cycles of 21 seconds negative pressure, 35- to 40-mmHg, and seven seconds normal pressure. Patients found the application relaxing and pleasant. The study proves that VACUMED both increases blood flow and microcirculation in the lower extremities and has a lymph drainage enhancing effect and is used for post-operative treatment of edema. n. |

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| **Reference No.** | 69 |
|---|---|
| **Bibliographic Data** | Lindsay, B.: Vacumed Therapy (LBNP) for Peripheral Arterial Disease (PAD), and Leg Disease. 2008, London. Unveröffentlicht. [A.2] |
| **Quality of evidence** | 2a |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Ten patients with diagnosed peripheral arterial occlusive carcinoma (pAVD, Claudicatio intermittens) in standard medical care, pain-related shortening of the possible walking distance and excluded multimobility were treated with VACUMED in a pilot study while maintaining normal life routines. pAVD is characterized by a massive impairment of quality of life. In those over 55 years of age, 5% of all men and 2.5% of all women are affected (UK data); incidence increases with age. pAVD is also a marker for secondary diseases (myocardial infarction, stroke, crit. Ischemia with need for amputations at a cost of 6,600 to 11,000 Brit. Pounds [source in text]. The endpoint of the study was defined as a 50% improvement in pain-free walking distance. Two applications per week of negative pressure of -20 to -44 mmHg and cycles of 6 to 8 seconds of negative pressure and 7 - 8 seconds of atmospheric pressure were administered, corresponding to a treatment program predefined by the manufacturer (#5). During the study, four patients dropped out due to too far from the clinic, misdiagnosis (nerve disease), drop in blood pressure during application and Ca surgery. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | While the average pain-free walking distance was 215 yards (197 m) at the beginning of the study, patients were able to walk an average of 837 yards (582 m) pain-free after completion of the study. This corresponds to an average increase of 195.43% (100% minimum - 500% maximum). In addition, patients reported more positive sensations of warmth in their feet, less cramping at night, and an improved ability to climb stairs. Quality of life and participation in life improved significantly in all patients. |
| **Conclusions** | VACUMED is suitable to reduce the priphyseal underperfusion in pAVD (I - IV Fontaine) and the pain resulting from it in elderly patients, to increase the walking distance and to improve the patients' quality of life. |
| **Limitations** | Patients with mulitmobidity, unstable angina, implants, severe renal problems were excluded. |
| **Summary** | In the case of peripheral circulation disorders (pAVK), even in a small collective of n = 6, there is a clear result: 100% of all those who completed the study have a significant improvement in pain-free walking distance (195% median). The program parameters (program "5" VACUMED, characterized by negative pressure cycles of 5 bsi 8 seconds, pressure phases of 7 and 8 seconds and suppression to - 44 mmHg (increasing) were confirmed as effective. The study proves that VACUMED increases blood flow and microcirculation in the lower extremities and can be used to treat chronic wounds. |

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| **Reference No.** | 70 |
|---|---|
| **Bibliographic Data** | Hamptom, Sylvie: Assesemant of the benefits of Vacumed in wound healling. 2008, Eastbourne. Unveröffentlicht. [A.3] |
| **Quality of evidence** | 2c |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | VACUMED was tested at the Eastbourne Wound Healing Centre, UK, on a 71 year old patient who had been suffering from arterial disease for 45 years. The tissue of the right leg was already so damaged that no pulse could be detected by Doppler, the skin was already discolored and an amputee was suggested. The patient suffered from continuous pain, which manifested itself as excruciating, especially at night. As part of the assessment, the patient received one application of VACUMED for 30 minutes on each of eight consecutive days. During one application, the oxygen content of the blood was measured every five minutes. The pain score was also measured on a scale from 0 (no pain) to 10 (excruciating pain). |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | During the applications, the oxygen saturation in the tissue regularly increased from 92% to 100%. The sensation of pain was reduced from 10 to 0 and remained at this level for another four weeks after the end of the applications. The appearance of the skin clearly normalized. Amputation could be avoided. |
| **Conclusions** | VACUMED increases the oxygen content in the blood in case of insufficient O2 saturation, reduces pAVD-induced continuous pain, improves blood flow to already damaged tissues and can help prevent amputations. |
| **Limitations** | none |
| **Summary** | A critical single case observation at a wound center in England shows that VACUMED increased blood O2 saturation, revascularized ischemic tissue, avoided amputation, and reduced pain score from 10 (excruciating) to 0 (no pain) in a palliative 72-year-old patient with stage IV pAVD (Fontaine). The study demonstrates that VACUMED increases blood flow and microcirculation in the lower extremities and can be used in the treatment of chronic wounds. |

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| **Reference No.** | 71 |
|---|---|
| **Bibliographic Data** | Balogh, György: Dermatological applicationof Vacumed device for the treatment of chronic venous insufficiency for patients in stadium III - IV. 2001, Budapest. Unveröffentlicht [A.4] |
| **Quality of evidence** | 2c |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | 18 patients, eleven women and seven men, with chronic venous insufficiency stage III and IV received VACUMED for ten times 20 minutes with -45 mbar, six seconds of negative pressure and six seconds of normal pressure during 30 days of observation in the dermatology department of the St. Stephan Hospital in Budapest, while the standard medication was maintained. The control group consisted of a comparable collective of 18 patients, in whom the standard medication was also maintained. The women were younger on average (47.1 years on average) than the men (62.5 years on average) , since CVI regularly manifests earlier in women as a result of weak connective tissue. CVI III and IV is a postthrombotic syndrome and is characterized by marked edema and tissue damage (ulcus cruris venosum). No exclusion criteria or contraindications were defined for the application observation. The parameters defined were body weight, waist circumference, hip circumference, and thigh and ankle circumference of the left leg in each case. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | In stages III and IV, CVI has already manifested itself in such a way that there are hardly any reductions in body part circumferences. Nevertheless, after VACUMED, with only small reductions in weight (0.4%), an average 2% reduction in abdominal circumference was measured, 2.3% in hip circumference, 4.7% in thigh circumference and 2.1% in ankle circumference, which is considered by the experts as a positive shift of the lymphatic load from the periphery to the trunk. Also observed was an improvement in walking distance and a significant improvement in wound healing. Strikingly, the use of VACUMED reduced the typically depressed mood of CVI patients (mental, euphoric effect). During the 30-day application period, one patient had biliary colic, another reported worsening of hemorrhoids, and another reported dizziness. Since these are individual anecdotal reports not mentioned in any other study or by any operator to date, they should be considered coincidental and not systematic. |
| **Conclusions** | VACUMED can help reduce edema and heal wounds in stage III and IV CVI beyond standard medication and has a positive effect on patients' underlying depressed mood. |
| **Limitations** | none |
| **Summary** | CVI is a widespread disease of the venous system that affects about 90% of all adults. It passes through several stages and, with increasing life expectancy, leads in more and more people to stages III and IV. which is characterized by massive edema formation and "open" legs (venous ulcerations). The standard therapies of the leilines (manual lymphatic drainage, compression bandaging, comp0ression stocking and cosmetic care of the damaged tissue try to stop further progression. The application observation presented here shows that VACUMED can also lead to a positive shift in body fluids, edema reduction, and psychological brightening in patients, with ten applications over a 30-day period. The study proves that VACUMED both increases blood flow and microcirculation in the lower extremities and has a lymphatic drainage enhancing effect and can be used in chronic venous disease stage III and IV. |

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| **Reference No.** | 74 |
|---|---|
| **Bibliographic Data** | Raath, Russel P.: Motivation for Vacumed Treatment. Mucklenbeuk, Pretoria, 2012. Unveröffentlicht [A.5]. |
| **Quality of evidence** | 5 |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | In a statement, the chief physician, anesthesiologist and pain management specialist, presents the indications for which the VACUMED is used successfully ("...with great success") at Jacaranda Hospital, Muckleneuk, South Africa. These include 1, non-healing vascular or diabetic ulceratrions, 2. poorly healing post operative wounds, 3. diabetic foot syndrome and gangrene, 4. peripheral neuropathy ("burning feet"), 5. microvascular and vascular disease and resulting reduced perfusion, 6. chronic pain of various causes and 7. dicogneous pain, 8. failed back surgery syndrome (FBSS), 9. oedema of all types including post traumatic, post surgical, post thrombotic and CVI, 10. sports injuries or other dislocations including 11. bone fracture, 12. recovery acceleration after intense sports, 13. restless legs syndrome. The rationale behind VACUMED therapy is stated to be the stimulation of collateral vessel growth (capillarization) and the improvement in microperfusion brought about by VACUMED. On average, patients in the clinic receive 30 minutes of VACUMED each for five consecutive days, with two applications per patient per day given in extreme cases. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | The following indications of VACUMED are confirmed: arterial diseases (including RLS), venous diseases (including edema), venous and arterial chronic wounds (including DFS), pain. For the first time, the application of VACUMED is mentioned in FBSS and discogenic pain syndrome, although the causes of pain are outside the treatment area, lower body. This also applies to its use in fractures. The cost of a VACUMED application is estimated to be comparable to the cost of a medical consil. |
| **Conclusions** | In addition to improved microcirculation, capillarization promotion is also mentioned as a rationale. Obviously, fractures and post-operative conditions are not contraindications. |
| **Limitations** | The effect of VACUMED is seen exclusively in the periphery and microcirculation and cannot replace vascular surgery or eliminate occlusions in large vessels. |
| **Summary** | The practical report confirms the successful use of VACUMED in arterial diseases (including RLS), venous diseases (including edema), venous and arterial chronic wounds (including DFS) and in pain therapy. Of note is the application of VACUMED in FBSS and discogenic pain syndrome, although the causes of the pain are outside the treatment area, lower body. Also noteworthy is its use in fractures. Fractures and post operative conditions are not contraindications at Jakaranda Hospital. In hospitalized patients, VACUMED is also administered twice daily, depending on the severity of the condition. The study proves that VACUMED both increases blood flow and microcirculation in the lower extremities and has a lymphatic drainage enhancing effect and is used for complementary treatment in leg conditions and injuries. |

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| **Reference No.** | 76 |
|---|---|
| **Bibliographic Data** | Berbakov, Peter, Matt Cameron: 12 week Vacusports study conducted by the Sydney Swans AFL Football Club. Sydney, 2012. Unveröffentlicht (Ergebnisveröffentlichungen in der Publikumspressse) [A.6] |
| **Quality of evidence** | 2b |
| **Study description** | |
| · **Device** | |
| · **Objective** | 10 players used VACUSPORT 2 x per week after hard training or competition for recovery acceleration and were compared with 10 players of the same age and training condition. Parameters were different stretching ability, muscle pain, sleep and stress levels. Significant differences were shown in sit & reach score and sleep quality. Compared to the comparison group, improvements were also measured in Vertical Jump score, Average and General Muscle Pain Score, Wellness Score and Stress Level Score. Faster regression of lower limb hematomas was also observed. |
| · **Endpoint** | |
| · **Statistical measure** | |
| · **Patient Population** | |
| · **Number** | |
| · **Indications** | |
| · **Contraindications** | |
| **Results** | |
| · **Overall Outcome** | |
| · **Costs** | VACUSPORT leads to measurable improvement in AMF - players in the areas of stretching, muscle pain, and sleep and stress scores. |
| · **Adverse Events** | |
| · **Performance** | |
| · **Benefits** | |
| **Conclusions** | The positive effect of VACUSPORT applications was proven by performance diagnostics and in sleep and stress scores compared to the comparison group. |
| **Limitations** | The VACUSPORT device was only available for eight weeks. A longer use was desired, but did not take place. |
| **Summary** | In an internal study with 2 x 10 players at the American Football Champions performance center, it was shown that VACUSPORT provides measurable benefits in the areas of stretching, muscle pain, stress and sleep score, in contrast to the comparison group. The study proves that VACUSPORT (VACUMED) can accelerate the recovery of athletes after peak performance. |

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| **Reference No.** | 81 |
|---|---|
| **Bibliographic Data** | Schnik, S.: Prospektive Studie zur klinischen Wirksamkeit bei intermiittierender Unterdruckbehandlung bei Patienten mit pAVK im Stadium 2. Fallingbostel, 2008. Unveröffentlicht. [A.9] |
| **Quality of evidence** | 2c |
| **Study description**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | 23 patients between 61 - 82 years (average 75, 15 male, 8 female) with pAVK II (Fontain) and limitation of pain-free walking distance between 30 and 500 meters received an average of 14 applications (10 - 30) over a period of 3 - 12 weeks (average 5). Treatment parameters: 20 min, 5 sec. Negative pressure / 10 sec. normal pressure. Significant improvement in walking distance occurred in 19 patients (83%). No deterioration occurred in any patient. Standard measurement parameters: treadmill, 3 km/h, 4% or 12% incline. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | In the treatment of pAVK II, walking distance training has been well studied and is the gold standard; improvements in maximal walking distance of 150% can be achieved (training session > 30 minutes, 3 x weekly, > 6 months). However, only a minority of mostly elderly patients are willing to undergo systematic walking distance training for pain. In in-house patients, a 3-week inpatient rehabilitation with walking extension training results in an average of 40% extension. The present prospective study shows that the complementary use of VACUMED leads to an average improvement of 72% (increase rate 80%), although the improvements are not measurable immediately after one application. In the vast majority of outpatients who are unable or unwilling to undergo active walking distance training, VACUMED also leads to an increase in walking distance. Subjective patient responses to negative pressure treatment related to feeling of lighter legs (91%), pleasant warmth in lower abdomen/legs (74%), subjective improvement in walking distance (83%), no change in walking distance (17%), worsening of walking distance (0%), increase in back discomfort (13%), other intolerance reactions (0%). Parallel to the observation of the effects of VACUMED on the walking distance, a decrease of the pain at rest in the feet was observed in 3 pAVK patients, in whom the usual conservative and invasive therapy had already been exhausted. In two patients the nocturnal painkillers could be discontinued after application of VACUMED. |
| **Conclusions** | VACUMED is suitable to increase the pain-free walking distance of pAVK II patients, if no standardized active walking distance training can be performed. In connection with a shortened standardized walking distance training during 3-week inpatient rehabilitation, the average increase in walking distance can be significantly increased with complementary use of VACUSPORT. VACUMED is also well tolerated by elderly patients and helps to reduce rest pain. |
| **Limitations** | none |
| **Summary** | VACUMED can prolong the pain-free walking distance in elderly PAOD patients when standard walking distance training is not an option. VACUMED can also prolong the increase in walking distance in combination with systematic active walking distance training reduced to an inpatient stay in a rehabilitation clinic compared to isolated walking distance training. At the same time, VACUMED can reduce rest pain. This study demonstrates that VACUMED both increases blood flow and microcirculation in the lower extremities and can contribute to the increase in walking distance of patients with PAOD. |

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| **Reference No.** | 82 |
|---|---|
| **Bibliographic Data** | Jansen van Rensburg, A. , D. C. Janse van Rensurg, H. E. van Buuren et al. : The use of negative pressure wave treatment in athlete recovery. In: The South African Journal of Sports Medicine, Kapstadt, 2017; 29 [A.10] |
| **Quality of evidence** | 1 b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Regeneration after intensive training and competitions is just as important in competitive sports as the training itself. Here we investigate whether the use of VACUSPORT can accelerate recovery after intense training. 22 male cricket players were randomized into a treatment group and a control group. After an intense one-hour training session, the treatment group was administered a 30 - minute VACUSPORT application on the day of training and on each of the following two days. After fourteen days, the two groups were crossed over and the study was repeated. In the treatment group, heart rate and blood pressure decreased markedly during treatment and returned to baseline values after treatment. Lactate concentrations decreased significantly more in the treatment group (0.57 ± 0.23 mmol/l) than in the control group (0.78 ± 0.22 mmol/l), p < 0.001). Creatine kinase (CK) bieb similar in both groups. In the subjective assessment of the athletes, which was also examined, the treatment group achieved significant improvements in recovery score, perceived muscle feeling, fatigue, and recovery. The treatment group shows a higher energy and recovery status than the control group. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | VACUSPORT helps immediately after an intense workout and on the two consecutive days, contributes to a faster recovery, which can be significantly measured in blood lactate and in subjective scores. This contributes to the ability to complete the next training session earlier than the control group and thus to achieve an increase in performance compared to the competition. In elimination competitions, the use of VACUSPORT can provide advantages. |
| **Conclusions** | VACUSPORT can shorten recovery after intense training or competition. |
| **Limitations** | In the study, VACUSPORT is applied only reduced (3 x 30 minutes in three consecutive days). Other studies with more applications also show a reduction of the CK value. |
| **Summary** | Vacusport can shorten the recovery after intensive training, which is shown in this study by a faster reduction of heart rate and blood pressure, by the faster reduction of blood lactase and by the recording of subjective standard scores of modern training theory and performance diagnostics compared to the control group (cross over / randomized). The study proves that VACUMED has a lymph drainage enhancing effect and can be used for faster recovery of athletes after peak performance. |

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| **Reference No.** | 83 |
|---|---|
| **Bibliographic Data** | Maior, A. S., Marcio Tannure, Fabio Eiras et al.: Effects of intermittent negative pressure and active recovery therapies in the post-match period in elite soccer players: A randomized, parallel arm, comparative study. In: Biomedical Human Kinetcs, 2020; 12, 59-68 [A.11] |
| **Quality of evidence** | 1 b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | This study compared the effects of intermittent negative pressure therapy (INPT) with VACUSPORT vs. active recovery therapy (ART) on post-game physiological parameters. Parameters included serum CK level and lower limb skin temperature. For this purpose, 20 (n=20) comparable healthy male professional soccer players of a Brazilian first division soccer team were enrolled and randomized for a parallel, open comparative study. Players were eligible to participate if they were nonsmokers (in the past 3 months or longer); had no cardiovascular or metabolic disease, recent musculoskeletal injury (in the past 6 months), or pain in any body region; were not allowed to take anabolic steroids, medications, or drugs that might impair physical performance (self-report). After participating in 2 soccer matches, they were randomly assigned to 2 groups (n = 10) to receive a 30-minute session of INPT (-33 to -52 mmHg, 6-9 sec negative pressure, 6-9 sec normal pressure) or ART (self-myofascial release, mobility, and bicycle ergometer exercises). The intervention was performed after a match with assessments immediately before and after the intervention and again 24 h after the intervention.The measurements took place in a standardized manner at the same time and under the same external conditions. A significant interaction effect ($F_{2,36} = 4.503$, $p = 0.018$, $\eta^2 = 0.130$) was observed, indicating that the CK decrease from before the intervention to 24 h after the intervention was greater in the INPT group than in the ART group . Thermographic measurement of skin temperature was also significantly lower after INPT than after ART. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Vacusport reduces CK levels after intense athletic competition, contributing to faster recovery compared to the control group. Differences of >0.7 °C in skin temperature between elite soccer players (INPT vs. ART) contribute to the recovery process from increased blood flow in the microcirculation, reduction of edema, removal of exudate, cell proliferation, and angiogenesis, which may lead to faster neuromuscular recovery, reduced muscle tension, and reduced pain sensation. |
| **Conclusions** | VACUSPORT measurably shortens recovery after intense competitions. |
| **Limitations** | The study group (n) is determined by the number of players of a football club that can be compared. |
| **Summary** | VACUSPORT shortens recovery after intense competition in Premier League soccer players, as measured by faster CK reduction and faster decrease in skin temperature. The study proves that VACUSPORT (VACUMED) increases blood flow and microcirculation in the lower extremities as well as has a lymphatic drainage enhancing effect and is used for faster recovery of athletes after peak athletic performances. |

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| **Reference No.** | 84 |
|---|---|
| **Bibliographic Data** | Orletsky A.K., D.O. Timtschenko: Use of devices for intemittent negative pressure therapy for treatment of athlets. Moskau,2009 (Unveröffentlicht. Dt. Übersetzung teilveröffentlicht in: Deutsche Zeitschrift für Sportmedizin, 2011, 2). [A.12] |
| **Quality of evidence** | 1 b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | This study compared the effects of intermittent negative pressure therapy (INPT) with VACUSPORT vs. active recovery therapy (ART) on post-game physiological parameters. Parameters included serum CK level and lower limb skin temperature. For this purpose, 20 comparable healthy male professional soccer players from a Brazilian first division soccer team were enrolled and randomized for a parallel, open comparative study. Players were eligible to participate if they were nonsmokers (in the past 3 months or longer); had no cardiovascular or metabolic disease, recent musculoskeletal injury (in the past 6 months), or pain in any body region; were not allowed to take anabolic steroids, medications, or drugs that might impair physical performance (self-report). After participating in 2 soccer matches, they were randomly assigned to 2 groups (n = 10) to receive a 30-minute session of INPT (-33 to -52 mmHg, 6 - 9 sec of UNinferior pressure, 6 - 9 sec of normal pressure) or ART (self-myofascial release, mobility, and bicycle ergometer exercises). The intervention was performed after a match with assessments immediately before and after the intervention and again 24 h after the intervention.The measurements took place in a standardized manner at the same time and under the same external conditions. A significant interaction effect (F2,36 = 4.503, p = 0.018, η2 = 0.130) was observed, indicating that the CK decrease from before the intervention to 24 h after the intervention was greater in the INPT group than in the ART group . Thermographic measurement of skin temperature was also significantly lower after INPT than after ART. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Vacusport reduces CK levels after intense athletic competition, contributing to faster recovery compared to the control group. Differences of >0.7 °C in skin temperature between elite soccer players (INPT vs. ART) contribute to the recovery process from increased blood flow in the microcirculation, reduction of edema, removal of exudate, cell proliferation, and angiogenesis, which may lead to faster neuromuscular recovery, reduced muscle tension, and reduced pain sensation. |
| **Conclusions** | VACUSPORT measurably shortens recovery after intense competitions. |
| **Limitations** | The study group (n) is determined by the number of players of a football club that can be compared. |
| **Summary** | VACUSPORT shortens recovery after intense competition in Premier League soccer players, as measured by faster CK reduction and faster decrease in skin temperature. The study demonstrates that VACUMED increases blood flow and microcirculation in the lower extremities as well as having a lymphatic drainage enhancing effect and is used for post-operative treatment. |

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|---|---|
| **Reference No.** | 88 |
| **Bibliographic Data** | Naude, L., J. Swanepol: Intermittent Vacuum Therapy. Applying Space Technology to Wound Care. In: Poster EWMA Congress (European Wound Manager Association), Amsterdam, 3.-5- Mai, 2017 [A.13] |
| **Quality of evidence** | 3 |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The aim of this study is to evaluate Intermittent Vacuum Therapy (IVT) as a complementary application in the therapy of complicated wounds and sports injuries within advanced wound care. For this purpose, 82 patients received IVT applications in addition to standard care. Inclusion criteria were: Wounds with delayed or slow healing over a period of more than two months. Etiologically, diabetes, vascular insufficiency, neuropathy, trauma, postoperative wounds (muscle flaps), and ligament tears (grades 1 - 3) were included. Distribution: diabetic foot ulcerations (33), vascular ulcerations (31), lymphedema (4), post operative non-healing wounds (4), athletes with ligament tears (10). The treatment protocol provided: Wound bed preparation according to Wound Bed Preparation Guideline (Sibbald, R.G. et al.: Optimizing the Moisture Management Tightrope with Wound Bed Preparation, In: Wolters Kluwer Health, Advances in skin & Wound Care, 2015, Vol. 28, pp. 466-476), treatment with IVT according to User Manual VACUMED, application time of IVT: 30 minutes, number of IVT applications 4 to 10. The results (pre /post) will be presented to Congress as images. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | The presentation concludes that intermittent vacuum therapy (IVT) as adjunctive therapy has a significant impact on the overall healing time of wounds as well as the quality of life of patients. All patients showed a significant decrease in pain levels and improved mobility. Wound healing improved and edema decreased significantly in all patients. Patients with neuropathy experienced an improvement in sensory perception. Athletes with torn ligaments were able to start their training program earlier |
| **Conclusions** | IVT can accelerate healing of chronic wounds as a complementary therapy. |
| **Limitations** | The presentation shows the use of IVT in 82 specific cases. The study is to be evaluated as an evidence study and is not randomized. |
| **Summary** | In a presentation to the EUMA - Congress, 2017, Amsterdam, it was shown on the example of 82 patients that VACUMED as a complementary therapy to standard care in chronic wounds (> two months wound healing delay) significantly initiates and accelerates wound healing. Pain levels are reduced, mobility is improved, edema decreases. In case of concomitant neuropathy, sensory perception increases. The quality of life of patients has been improved. In the case of torn ligaments, VACUMED leads to faster healing. The study proves that VACUMED increases blood flow and microcirculation in the lower extremities and is used for complementary treatment of chronic wounds. |

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| **Reference No.** | 89 |
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| **Bibliographic Data** | Zellner, M.: Postoperative Lymphstauung in der Urologie. Intermittierende Vakuumtherapie erste Erfahrungen und Ergebnisse. Vortrag in: 2. internationales IVT Symposium, Frankfurt 2015. Unveröffentlicht. [A.14] |
| **Quality of evidence** | 2a |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Prostate carcinomas have the highest incidence among cancers (ahead of lung, colon and bladder cancers) and lead to frequent complications after radical prostatectomy / cystectomy due to the formation of lymphocele. The standard therapy is manual lymphatic drainage, which is regularly supplemented by the use of apparative lymphatic drainage (intermittent ascending compression therapy). In a study at the Urology Department of the Johannisbad Fachklinik, Bad Füssing, it was investigated whether the complementary use of IVT with the VACUMED device leads to an increase in efficiency. For this purpose 56 patients after prostatectomy (n=56, right 32, left 37, both 13) and 11 patients after cystectomy (n=11, right 4, left 9, both 2) were treated adjuvantly with VACUMED. The results were recorded by volumetry in $cm^3$ pre- and post and compared with the historical collective. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Standard therapy achieves a reduction in the extent of lymphoceles of - 32% (mean - 11.6%) in the historical collective. In the study group, the reduction was - 40.9% (mean - 39.9%). Surgical treatment of the lymphocele, which necessitates transfer of the patient to the acute hospital, delays convalescence and reduces the revenue (DRG!) of the acute hospital, is thus potentially avoidable. |
| **Conclusions** | VACUMED increases lymphatic drainage and enhances the efficiency of post-operative care after prostatectomy / cystectomy. |
| **Limitations** | The study is to be considered a pilot study and is not randomized. |
| **Summary** | In a study of 67 patients after prostatectomy / cystectomy, it is shown that the adjuvant use of VACUMED increases the efficiency of standard therapy in the frequent complication in the form of lymphocele formation by 28% compared to the "historical" collective. There was no specific incident during the administration of VACUMED. The study proves that VACUMED has a lymph drainage promoting effect and is used in the treatment and prophylaxis of post-operative edema. |

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| **Reference No.** | 90 |
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| **Bibliographic Data** | Tuganbenov T., N. AShimov, G. Saipiyeva: Exerience in the application of interval vacuum therapy with Vacumed device in complex treatment of lower extremity trophic ulcers. In: Journal of clinical Medicine of Kazakhstan. 2014 (32):60-64 [A.16] |
| **Quality of evidence** | 2a |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The study investigates the effect of IVT with VACUMED on phlebostatic genesis in comparison to the per se known Negative Pressure Therapy (NPT) with suppressions of up to -125 mmHg in the treatment of chronic ulcerations of the lower extremities. For this purpose, at the Department of Surgery, Lezney No. 2 (Department of Surgery of JSC "NSMC", Astana) 5 patients were recruited (2 male, 3 female) aged from 24 to 73 years (mean 53.6). The underlying disease varied from 2 to 38 years; ulcerae persisted from 2 months to 24 years and ranged in size from 2.5 to 300 $cm^2$, 4 of which were exudative. The ulcerations were accompanied by severe impairment of phlebodynamics (edema, pain syndrome, induration, signs of varicose veins/dilatation of truncal veins); the depth of the wounds ranged from 0.5 to 1 cm. Patients received 10 sessions of VACUMED, 20 minutes each, to -60 mbar. They kept their standard dressings on during VACUMED applications; the use of protelytic enzymes was waived. The aim of the study was the effect of VACUMED on the regenerative processes characterized by 1. ulcer size, 2, edema reduction, 3. granulation/epithelialization. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | A significant reduction in the dimensions of the wound pre- and post-intervention of up to 90% was observed in all patients. Epithelialization occurred in the range of partial to complete in all patients. Subjectively, all patients noted a reduction or disappearance of pain or heaviness in the legs and an increase in balancing tolerance. No complications occurred in any case and no corrective treatment was needed. |
| **Conclusions** | IVT with VACUMED is an effective treatment method for trophic ulcerations of various origins. This is especially true for patients who have developed resistance or intolerance to other forms of therapy. VACUMED also has a pronounced effect on the general condition of patients in the form of increasing stress tolerance, reducing pain (even during dressing) and improving general well-being. |
| **Limitations** | None. The study is to be evaluated as a pilot study |
| **Summary** | The study shows the effect of the use of IVT in chronic wounds of different pathogenesis in five patients. In all patients, IVT leads to the initiation of granulation and epithelialization (partly complete) and to a significant reduction in the size of the wounds (up to 90%). All patients have less pain. Concomitant edema is reduced, exercise tolerance and general well-being are increased. There was no intolerance in any case. The study proves that VACUMED increases blood flow to the lower extremities and microcirculation and can be used in the treatment of chronic wounds. |

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| **Reference No.** | 91 |
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| **Bibliographic Data** | Naude, L.: ASSESSING THE EFFECTS OF LOWER BODY NEGATIVE PRESSURE THERAPY (LBNPT) IN THE TREATMENT OF LOWER LIMB OEDEMA. Poster und Vortrag in: EWMA – GNEAUPP (European Wound Manaer Association), Madrid, 2014 [A.17] |
| **Quality of evidence** | 2c |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The study investigates the effects of IVT with the VACUMED device in the treatment of edema and lymphedema. It is based on data from the Advances Lower Lim band Wound Management Centre, Pretoria , South Africa. Thirty patients (n=30) were recruited with lymphedema (23%), edema associated with venous hypertension (10%) and traumatic edema (67%). All patients had a differential diagnostic complete vascular examination including foot pulses, ABI (using Ability Duplex-Dopler device), limb circumference (mid-thigh, calf, ankle), oxygen saturation (before and after IVT session), standard pain score of 0-10. Patients with wounds were measured by longest width, longest length, and depth. Patients received 30-minute sessions of VACUMED with negative pressure of -38 mmHg - -50 mmHg. Sessions were performed either daily for 5 days with 2 days of rest or every other day. Wounds were treated according to the wound bed preparation guideline. Between sessions, patients were required to wear compression bandages or compression stockings. Circumference measurement took place on days 1,5, 10, 12, and 15. Oxygen saturation was measured before and after each session. Pain score was determined on each session day. In parallel, a survey was conducted regarding daily activities, exercise, pain perception in general, and sleep duration and quality. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | There was a case-dependent decrease in leg circumference between 4 cm and 12 cm (peak 18% reduction). Immediately after the 30-minute VACUMED application, there was a circumference reduction between 0.5 cm and 2 cm. Oxygen saturation rate increases by 3-4% after each 30-minute session; after an average of 12 sessions, patients have a consistent 2% increase. Patients show improved mobility, less pain, decrease in wound size, decrease in inflammation. |
| **Conclusions** | IVT with the VACUMED device seems to be beneficial and time-saving in the treatment of lymphedema and edema. It leads to an additional reduction of edema besides standard therapy and compression stockings. Patients tolerate the treatment well and do not feel any physical pain during the treatment. The use of the technology saves time for professionals and reduces manual work associated with lymphatic drainage. The perfusion differences in the vessels can be proven by transcutaneous oximetry measurements before and after the treatment. |
| **Limitations** | Data acquisition, especially ABPI, is very time consuming. Measurement errors may occur depending on the practitioner measuring the legs. The study can be considered a pilot study. |
| **Summary** | In a specialized wound and vascular center in South Africa, it has been shown in 30 patients that VACUMED, when used for venous and post-traumatic edema as well as lymphedema, brings about an additional reduction in volume. A higher vascular perfusion can be proven by transcutaneous PO2 measurement. The application of VACUMED also reduces pain. As a fully-apparative application, VACUMED relieves the hospital staff. The study proves that VACUMED both increases blood flow and has a lymph drainage enhancing effect and can be used in the treatment of lymphatic and port thrombotic edema. |

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| **Reference No.**<br>**Bibliographic Data** | 92<br>Agopian-Simoneau, L.: Rapport d'etude Vacustyler. Marseille, 2008 (Unveröffentlicht)[A.18] |
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| **Quality of evidence** | 2c |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The study investigates the effect of Intermittent Vacuum Therapy (IVT) in dermatology on 18 female subjects (n=18) aged between 18 and 55 years. Inclusion criteria were normal or overweight of max. 20%, cellulite, venous and lymphatic congestion and unpleasant feeling of heaviness in the legs. Subjects received 15 IVT sessions of 30 minutes each, 2 times a week with the requirement to drink at least 2 liters of fluid per day. An initial examination (T0) and a final examination (T2) took place, whereby in particular the difference in the optical appearance of the cellulite on different body areas, the elasticity of the skin, skin dryness, water retention in the legs and the effect "heavy legs" were measured. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Subjectively, a regression of the cellulite syndrome in the area of the hips was noted by an average of 24%; in the area of the thighs by 28%; improvement of the tone of the skin on the hips by 28%; improvement of the tone of the skin on the thighs by 28%; decrease in skin dryness of 31%; water retention on the legs by 56%. The effect of "heavy legs" decreased by 56%; elimination improved by 44%. Circumference measurement was measured by tape pletysmography in cm: Decrease at the hip average 117 mm (up to 550 mm), decrease at the thighs 50 mm (up to 200 mm), decrease at the lower thigh 42 mm (up to 125 mm). Statistical effectiveness on cellulite of 78% is noted; improvement of skin firmness of 78%; improvement of skin softness of 83%; decrease in the effect of "heavy legs" of 78%; decrease in water retention in the legs of 67%; increase in excretion of 67%. Psychosensory effectiveness of relaxation was stated to be 94%. The application of IVT was positively tolerated clinically by all 18 subjects (100%). No negative effects associated with IVT were noted. |
| **Conclusions** | IVT is effective in the area of cellulite, which is essentially a local lymphatic circulation disorder. Biometrologically, a decrease in external skin features and skin dryness can be observed, as well as an increase in skin tone and firmness, which indicates an improvement in the performance of the physiological muscle pump. |
| **Limitations** | The study was not randomized and must be considered as outcome research. |
| **Summary** | In a study, 18 female patients with local lymphatic circulation disorder (cellulite) and veno-lymphatic edema were each administered 15 sessions of IVT (2 x weekly). The results showed a decrease in cellulite on the hips and thighs, improved skin hydration and an increase in connective tissue structures. The study proves that IVT has a lymphatic drainage promoting effect and can contribute to a firming of the skin turgor. |

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| **Reference No.** | 94 |
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| **Bibliographic Data** | Strauss, A.: Fallstudie zur Verwendung von VACUMED bei pAVK III und IV Patienten. Düsseldorf, 2001. Unveröffentlicht. [A.20] |
| **Quality of evidence** | 3a |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | In a very early application observation at the Dominikus Hospital, Düsseldorf, in 2001, patients with arterial occlusive disease in the stage of chronic, critical ischemia (Fontaine stage III and IV) were treated with the VACUMED in the angiology department in the period from 17.5. to 2.7.2001. To verify the efficacy, acral pulse measurements at the toes with LLR Periquant 815 (Gutmann Company) as well as transcutaneous oxygen pressure measurements (Radiometer Company) were performed. The applications consisted of an average of 6 sessions of 20 minutes each and negative pressure values up to - 50 mmHg. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Acral pulse measurement shows an increase in pulse amplitude and TcPO2 (transcutaneous substance pressure) in pAVK III and IV patients at the foot. The values correlate with the increase in negative pressure. No side effects occurred in any patient. |
| **Conclusions** | Application of IVT during critical ischemia results in an increase in pulse amplitude at the foot and increases metabolic pressure. Both results indicate an increase in blood flow during negative pressure application. |
| **Limitations** | IVT is also well tolerated in pAVK III and IV patients up to a negative pressure of 50 mmHg. |
| **Summary** | This is an important application observation to indicate the tolerability and outcome of the use of VACUMED in a specific indication. |

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| **Reference No.** | 95 |
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| **Bibliographic Data** | Campisi, C., F. Boccardo, C.C. Campisi: Lymphatic Microsurgery and Intermittent Suction Therapy (VACUMED) for Lymphoedema. Genua. In: Fachvortrag auf dem 2. Int'l. IVT Symposium, Frankfurt, 2015. Unveröffentlicht. [A.21] |
| **Quality of evidence** | 3b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | In cases of pronounced primary and secondary lymphedema, microsurgical anastomoses are made between lymphatic vessels and veins (LVA = Lymphatic - Venous Anastomoses) or between lymphatic vessels and veins and lymphatic vessels ((LVLA = Lymphatic - Venous - Lymphatic Anastomoses). Pre- and postoperative antibiotics and then long-acting penicillin are given for 1-2 years. In parallel, functional multilayer bandages are applied for the first week and then elastic supports (stockings, sleeves) for at least 3-5 years. Adjuvant mechanical lymphatic drainage (intermittent ascending compression therapy) is applied for the two weeks before surgical intervention. Postoperatively, manual lymphatic drainage for the first 3-5 days. Follow-up consists of periodic clinical assessments (volumes, measurements of circumferences, etc.) and instrumental evaluations by lymphoscintigraphy. Since 2004, at the Department of Surgery Section of Lymphology & Microsurgery (Operative Unit of Lymphatic Surgery, Operative Unit of Plastic & Reconstructive Surgery, IRCCS) of the University Hospital San Martino - IST National Institute for Cancer Research,Genoa, Italy, patients additionally receive VACUMED in the phase before surgery (Pahse 1, 6 - 12 months), immediately after the mircrosurgical procedure (Pahse 2, 1 week) and in the postoperative rehabilitation (Phase 3, 3 - 5 years). |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | "...Lymphatic microsurgery combined with Intermittent Suction Therapy (VACUMED) have highly significant results for effective and long-term treatment of peripheral lymphedema." |
| **Conclusions** | VACUMED assists in the preparation of microsurgical LVA and LVLA constructions and can also be used for early postoperative care and long-term rehabilitation of lymphedema patients. |
| **Limitations** | Practice Report |
| **Summary** | In cases of pronounced lymphedema, microsurgical interventions are planned to form anastomoses between lymphatic vessels and veins or between veins and lymphatic vessels. VACUMED is suitable adjuvantly both in preoperative preparation and immediately after surgery for early mobilization and long-term rehabilitation. The study proves that VACUMED promotes lymphatic drainage and can be used both early - post-operatively - and for long-term rehabilitation. |

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| **Reference No.** | 97 |
| **Bibliographic Data** | Stratmann, B.: IVT on diabetic macroangiopathy. Bad Oeynhausen. In: Fachvortrag auf dem 2, Int'l IVT-Symposium, Frankfurt, 2105 (teilweise veröffentlicht als Poster 283, 50. Jahrestag Deutsche Diabetische Gesellschaft, 2015, Berlin) [A.26; A.30] |
| **Quality of evidence** | 1b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Patients with diabetic foot syndrome and critical ischemia often present with severe pAVD without invasive intervention options to improve circulation. The prevalence is 10%-30% in >50 year olds. Critical limb ischemia (CLI) leads to limb amputation, multi morbidity and death. In Germany alone, more than 60,000 amputations occur annually. At the Heart and Diabetes Center NRW, Ruhr University Bochum, Bad Oeynhausen, Germany, 2 x 25 already out-treated (palliative) patients with type 1 and 2 diabetes mellitus and pAVK in stage II to IV (Fontaine) and a TcPO2 of < 25 mmHg aged 18 to 80 were to be recruited for a randomized study (VACUMED REvascularization Trial. CIV-14-06-012160, Prüfplancode: VAC2014V1.2, AZ Ethics Committee; 38/2014). Vascular revascularization or catheterization was no longer possible in all patients. The following concomitant conditions were tolerated for the study: Pacemaker, DFS (diabetic foot syndrome), CAVK (cerebral AVK), CAD (coronary artery disease), AF (atrial fibrillation), rethinopathy (retinal disease, also diabetic), DPN (diabetic neuropathy), hypertension, dyslipoproteinemia, and renal insufficiency (G3). Exclusion criteria were defined as severe heart disease (NYHA II-IV), same-day dialysis, phlebothrombosis, PTA/PTCA/bypass during therapy, iliac artery occlusion, pregnancy. Parameters measured were TcPO2 and ABI. Randomization was to the -mbar or -10 mbar (comparator therapy) treatment group. Four patients aged 68 to 89 years (mean 84, male, 1 female) who participated in the study were presented in the technical lecture. Baseline TcPO2 before treatment averaged 23 mmHg on the left (10, 35, 30, 18) and 20 mmHg on the right ( 33,27,17,4). Patients received up to 14 therapeutic VACUMED sessions (minimum 5) with a four-phase preprogrammed treatment program to -56 mm bar. |
| **Results** | After application of the IVT sessions with VACUMED, the TcPO2 on the left side was on average |
| **Overall Outcome** | 46 mmHg (55, 45, 40, 45), right 30 mmHg (35, 30, 25, 29). On average, perfusion improved by 750% (albeit with a large standard deviation of +/- 1073%). If two readings with over 1000% improvement are excluded, the average perfusion improvement is 201 +/- 131%. In the -10 mmHg group, a TcPo2 measurement is relevant to the study; here, too, a significant improvement occurred (183% in relation to the value at study inclusion). In one patient, the aortic valve could be replaced based on the treatment outcome. In all patients (further) amputation could be avoided. No patient experienced intolerance of the IVT application. No adverse or serious adverse reportable events occurred during the study. |
| **Conclusions** | IVT with the VACUMED device leads to a significant improvement of perfusion in out-of-therapy patients with critical ischemia, which has been proven by oxygen pressure measurements (TcPO2 ). In the case of reduced perfusion, an increase occurs even with the administration of lower negative pressure phases (-mbar). Typical concomitant conditions such as CAVK, CAD, AF, DPN, hypertension and renal insufficiency are not contraindications for IVT. Amputations could be avoided. Overall, conservative therapy of pAVD in diabetic foot syndrome and critical ischemia by IVT shows a very good effect on wound healing even in elderly and multi-morbid patients. The improvement in nutritive oxygen supply is of a similar magnitude as after recanalization of the vessels. |

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| **Limitations** | This study was unsuccessful to recruit because of the inclusion criteria, which in principle requires a palliative approach. Any vascular intervention, whether vascular surgery or angioplasty, is contraindicated for the purposes of the study because it improves the perfusion situation and affects the endpoint TcPO2 improvement. The study was not completed due to lack of allocation of additional palliative patients. The interim result presented here can be considered alternatively as 2c, Outcome Sudie. |
| **Summary** | For a randomized study on the effect of IVT with the VACUMED device in critical ischemia, 2 x 25 already out-treated multimorbid patients with pAVK II - IV (Fontaine) and a TcPO2 < 25mmHg will be recruited. In a technical lecture at the 2nd Int'l. IVT - Symposium, which was partly published as a poster at the annual meeting of the German Diabetic Society, it is shown by the example of four patients with an average age of 84 years that IVT causes an increase in TcPO2. The improvement in perfusion is 201 +/- 131% on average. A significant improvement also occurred in the -10 mmHg comparison group (183% in relation to the value at study inclusion), demonstrating that in the presence of reduced perfusion, even low negative pressures improve TcPO2. Typical concomitant conditions such as CAVK, CAD, AF, DPN, hypertension, and renal insufficiency are not contraindications for IVT. Further amputations were avoided in these patients. In one case, participation in the study led to stabilization of the patient so that an aortic valve could be replaced. The study had to be discontinued because no more patients could be recruited. The study proves that VACUMED promotes blood flow to the lower extremities and can increase perfusion in pAVK II - IV and critical ischemia. |

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| **Reference No.** | 98 |
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| **Bibliographic Data** | Alf, D., L. Butt: Anwednugnsbeobachtung zur Regeneration von Hochleistungsportlern beim Einsatz des VACUMED LBNPD (lower body negative pressure device). Essen, 2007 (teilveröffentlicht in: Medical Sport Network, 2007 (4;64-67))[A.29] |
| **Quality of evidence** | 2 b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | In high-performance sports, regeneration plays a decisive role. Those who regenerate better and faster can also train better and faster and more intensively and at the same time prevent an increased ability to injure due to intensive stress. The well-known standard procedures in regeneration include manual massages and / or manual lymphatic drainage. Both lymphatic flow and arterial-venous blood exchange are stimulated, muscle tone is reduced and the concentration of endorphins in the brain is increased. In a study at the Spot Medical Institute of the Olympic Training Center Rhine-Ruhr, Essen, it was investigated whether the continuous application of IVT with the VACUSPORT (VACUMED) leads to a measurably accelerated regeneration. For this purpose, 50 high-performance athletes of Olympic sports were recruited. The period of the study was defined as 12 weeks. The athletes of the individual sports trained in the same training group, with half of the respective training group being subjected to a 30-minute treatment with the VACUSPORT device (VACUMED) (-40 to -50 mbar, pressure/vacuum ratio = 7/5 sec) every 2 days. All athletes (both the VACUPORT group and the non-VACUSPORT group) had blood drawn 2 times per week before and after exercise, and ei parameters resting lactate (immediately before exercise), post-exercise lactate (immediately after the end of exercise), and CK, urea, uric acid, and leukocytes were measured. A lactate step test was performed with all athletes at the beginning and end of the study. In addition, all athletes were asked about their motivation and the subjectively perceived degree of recovery using a numerical rating scale before the start of each training session. The intervention group was also asked about their subjective opinion regarding the effectiveness of the VACUSPORT (VACUMED). |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | The studies show a reduction in resting lactate levels each before the start of exercise (1.48 mmol/l to1.59 mmol/l) in the VACUSPORT group and a reduction in urea ( 40mg/dl to 43 mg/dl) and uric acid concentrations ( 3.9 mg/dl to 4.85 mg/dl). A reduction in creatine kinase (262 U/1 to 284 U/1) was measured. White blood count values (leukocytes 6.2 TSD to 6.0 TSD) and postload lactate ( 8.24 mmo/l to 8.16 mmol/1) were within the range of measurement variation. In the area of the subjective feelings of the athletes (minimum score 1- maximum score 4), the athletes who experienced an application of the Vacumed device in addition to the generally implemented regeneration measures, show a significantly increased training motivation ( 3.2 to 2.8 points) a significantly better muscle feeling ( 2.7 to 2.1 points) and an overall improved regeneration ( 3.2 to 2.6 points). The athletes in the VACUSPORT group rated the effectiveness of this application as very high with 3.7 out of a possible 4 points. |
| **Conclusions** | The use of VACUPORT (VACUMED, 2 x weekly) during a training session lasting several weeks leads to a clearly measurable, improved regeneration. The performance and motivation as well as the subjective well-being of the athletes are increased. |
| **Limitations** | None |
| **Summary** | In a study (n=50), athletes who combine their training with VACUSPORT (VACUMED) applications show significantly faster recovery, as measured by better lactate levels, CK, urea and uric acid. VACUSPORT (VACUMED) leads to more subjective well-being in the athletes than in the comparison group, a significant increase in training motivation and better muscle feeling. The study proves that IVT shortens the athlete's recovery after sporting activities. |

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| **Reference No.** | 99 |
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| **Bibliographic Data** | Schink, S.: Die Intermittierende Unterdruckbehandlung mit dem VACUMD Gerät. Verträglichkeit der Behandlung. Fallingbostel, 2008. (Unveröffentlicht) [A.31] |
| **Quality of evidence** | 3 a (diagnosis) |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | At the cardilogic clinic for acute aftercare and rehabilitation of cardiac, circulatory, and vascular diseases (AHB), Fallingbostel, Germany, a total of 6,071 sessions of 20 minutes (-40 to -60 mbar, 2 to 3 sessions per week) with VACUMD were conducted on 1014 patients (13% of whom were outpatients) from June 1, 2004 to September 17, 2008. Patient characteristics: 41% women/59% men, mean age 68.3 years (of which 118 patients were at least 80 years, oldest patient 96 years). Patients with fresh leg vein thrombosis or infected wounds in the treatment area were excluded. The main indication was circulatory disturbance in the lower extremities. 70% of patients were diagnosed with pAVD; 22% had received bypass surgery or stent implantation in the iliac or leg arteries in the 3 months prior to VACUMD; 14% had stage I to III CVI; 9% had a wound in the foot or leg. As an associated condition, 57% had coronary artery disease; 23% had a myocardial infarction or severe heart attack (coronary syndrome, stent implantation) within the last three months before intervention; 17% had cardiac surgery within the last three months; 15% with heart failure (some severely impaired cardiac output); 12% have hypotensive blood pressure. 14% have pulmonary emphysema; (% show condition after carotid artery surgery; 7% condition after stroke; 3% aneurysm of abdominal aorta. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Complications were seen in one patient with a large inguinal hernia; here VACUMED led to a feeling of swelling in the hernia (treatment was discontinued). A second patient with a large surgical scar in the mid-abdomen also complained of this. These complaints did not occur in patients with extensive fresh surgical scars / wounds on the legs. |
| **Conclusions** | Cardiac diseases, including CHD, are not contraindications for VACUMED. Hypotension or fresh surgical scars or wounds are also not contraindications. Remaining contraindications are defined as: Fresh phlebothrombosis (up to 8 weeks old), infected wounds (where acute or chronic wounds have been treated without infection), pregnancy, significant inguinal hernia or abdominal wall incisional hernia. VACUMED is considered to be a safe treatment. |
| **Limitations** | none |
| **Summary** | A long-term study at a cardiological rehabilitation clinic shows in 1014 patients that VACUMED applications with suppressions of up to -60 mbar are well tolerated even in underlying cardiological diseases and fresh postoperative conditions. VACUMED is not administered in cases of fresh phlebothrombosis, infections in the wound area, pregnancy or significant inguinal hernia or abdominal wall scar hernia. The study proves that VACUMED is a safe therapy. |

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| **Reference No.** | 102 |
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| **Bibliographic Data** | Yildirim, B.: Application of IVT in muscular and tendinous injuries in professional soccer. Fachvortrag in: 2. Int'l. IVT Symposium. Moskau 2019. (Unveröffentlicht) [A.32] |
| **Quality of evidence** | 3 b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | In professional soccer, with a squad of 25 players, there is an average of 0.6 muscle injuries per player / season. Muscle injuries account for about 30% of all injuries and result in a loss of about 27% resulting playing time. Up to 97% involve the lower limbs, mainly the hamstrings (37%). Adductors (23%), quadriceps (19%), and lower leg muscles (13%). Regarding the classification of muscle injuries, there is the generally accepted Munich Consensus, which classifies 4 types. In addition, there is a generally accepted overview of the expected average return to play time (RTP) depending on the degree of injury when all medical-therapeutic measures are exhausted. This is carried out internationally at the highest therapeutic level for professional soccer players. The Bayer Leverkusen 04 soccer club has its own rehabilitation center under medical management. There, in addition to therapy with Traumeel, Actovegin, ACP (enrichment of blood plasma), injections and complex physiotherapy (also with apparatus and Shockwave therapy), IVT with the VACUSPORT (VACUMED) was used. The results are visualized and documented with the help of MRI (sometimes also US) and functional performance diagnostics. VACUSPORT is administered immediately after the injury and then regularly 1 to 2 times daily. In the lecture the effect of the complementary use of VACUSPORT on the RTP will be shown in the following injuries: small partial muscle tear (M. iliacus) type IIIa, M. adductor magnus type IIIa, M. biceps femoris type IIIa, moderate partial tear M. adductor longus type IIIb, subtotal proximal tendon tear M. rectus femoris type IV. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | The use of VACUSPORT shortens the expected RTP. In the small partial muscle tear (M. iliacus) Type IIIa, the Return to Training (RTT) was only 16 days and the RTP 20 days instead of the expected 36 days, shortening by 44%. For M. adductor magnus Type IIIa injury: RTT after 14 days, RTP after 18 days, expected 36 days, shortening 50%. M. biceps femoris type IIIa, RTP after 9 days, expected RTP 63, shortening 86%. For moderate partial tear of adductor longus muscle type IIIb, RTT was 16 days after injury, RTP at 21 days, expected 28-42 days, shortening of at least 25%. For subtotal proximal tendon tear M. rectus femoris type IV, RTP was after 42 days, expected 120 - 160 days, shortening of at least 65%. |
| **Conclusions** | In the case of muscle injuries, VACUSPORT (VACUMED) can be used posttraumatically immediately after injury in a complementary manner and leads to a significant reduction in RTT / RTP time (range between 25 and 86%) in the case of partial or subtotal attachments and detachments. Post traumatic conditions are not a contraindication. |
| **Limitations** | None |
| **Summary** | Muscle injuries are among the most common injuries in professional soccer, resulting in an average loss of 27% playing time per squad. Muscle injuries are treated at the highest level in professional soccer. Recognized study provide information on the expected return to play time (RTP). The complementary use of VACUSPORT can shorten the RTP by approximately 25 - 86% in addition to the generally practiced high level of medical care. This study demonstrates that VACUSPORT can be used in the area of post traumatic rehabilitation and can lead to a shortening of rehabilitation, especially in muscular injuries. |

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| **Reference No.** | 103 |
|---|---|
| **Bibliographic Data** | Thijssen, D. H. J., C. L. Atkinson, K. Omo et al.: Sympathetic nervous system activation, arterial shear rate, and flow-mediated dilation. In: Journal of Applied Physiology, 2014 (116:1300-1307) [A.33] |
| **Quality of evidence** | 1b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The sympathetic nervous system (SNS) plays a significant role in regulating vascular tone. Activation of the SNS may index cardiovascular disease and physiological aging. Previous studies have reported a correlation of the effect of shear forces applied to the endothelium and a resultant stimulation on the SNS, leading to immediate vasodilatation. The aim of this university study is to examine the effect of shear forces on the endothelium and the SNS, with shear forces triggered by IVT (VACUSPORT). For this purpose, 10 volunteer, healthy, recreationally active men (n=10) with an average age of 28 years (+/- 5), height of 178 cm (+/-8), and weight of 76 kg (+/- 9.4) were recruited. The studies took place on four consecutive days, during which, in addition to the administration of IVT to the lower half of the body (- 35 mmHg, days 1 and 2: 10 minutes; days 3 and 4: 30 minutes in the supine position), heat or additionally a compression cuff with a pressure of 75- to 220 mmHg was administered to one arm at a time to abolish the IVT-induced shear. Administration of the different applications was randomized. Vascular dilation (FMD flow-mediated dilation) was measured bilaterally before and after each test on the arms, using both plasma catecholamines (epinephrine and norepinephrine) from the blood and high-resolution ultrasound (10 MHz multifrequency) to measure the lumen arterial wall and continuous Doppler to measure flow velocity. Changes in central hemodynamics were measured using a finometer and photplethymography. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | A 10-minute exposure to VACUSPORT (VACUMED) results in an immediate increase in retrograde shear and a decrease in brachial artery FMD. This is true for both groups, heat and compression. Epinephrine release was significantly increased in both groups. HR was also significantly increased. No additional differences in mean, antegrade, or retrograde shear rate were noted with the 30-minute IVT exposure. |
| **Conclusions** | According to study proves the influence of IVT-induced shear forces on SNS stimulation, resulting in vascular dilatation. IVT alters central hemodynamics. Compared with a 10-minute IVT exposure, the vasculature adapts to a 30-minute application and does not inhibit endothelial function. Regulation of retrograde shear rate cannot be explained by changes in vascular tone alone but also by other mechanisms, such as pressure by wave reflection. Effects of SNS stimulation are specific to endothelial function. |
| **Limitations** | The study was conducted in healthy adults. Whether the results can be applied to other populations, especially groups characterized by an increase in SNS activity, remains open. Disease-specific studies would be required here. |
| **Summary** | In a study the influence of VACUSPORT (VACUMED) on SNS and endothelial function is shown. Central hemodynamics are altered by VACUSPORT, as evidenced by an increase in epinephrine levels and retrograde shear rate. The study demonstrates that VACUMED exerts shear forces that stimulate central nervous system and thus endothelial function. |

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| **Reference No.** | 105 |
|---|---|
| **Bibliographic Data** | Elnemr, A. A., N. M. Elkhateb, A. A. Mohamed. Et al.: The Effect of Lower Body Negative Pressure Device on Regeneration of Baskeball Players. Kairo, 2019 (unveröffentlicht) [A.34] |
| **Quality of evidence** | 3 |
| **Study description** | |
| · **Device** | |
| · **Objective** | |
| · **Endpoint** | In competitive sports, e.g. basketball, the regeneration of players is as important as the training itself. The state of regeneration is regularly measured by the concentration of lactase in the blood. At Helwan Univerity, Greater Cairo, Egypt, blood lactate was measured in 10 basketball players (n = 10) with an average age of 17.72 years (+/- 1.93), 77.17 kg (+/- 4.14) 184.77 cm height (+/-5.45) and a BMI of 19.89 (+/-2.23) each immediately after an intense graduated exercise (Bruce protocol) and then after a 30-minute VACUSPORT (VACUMED) application under medical supervision. |
| · **Statistical measure** | |
| · **Patient Population** | |
| · **Number** | |
| · **Indications** | |
| · **Contraindications** | |
| **Results** | All study participants tolerated the VACUSPORT applications well. The results show a significant decrease in lactate concentration from 8.8 mmol/L (+/- 2.1) pretest to 1.1 mmol/L (+/-0.36) (P<0.05). |
| · **Overall Outcome** | |
| **Conclusions** | The rapid decrease in lactate concentration, which is a lymphatic load, is the result of VACUSPORT-induced blood flow and lymphatic drainage promotion. This is triggered by rhythmic vascular dilation and compression of capillary vessels due to alternating exposure to negative pressure and atmospheric pressure. VACUSPORT leads to a rapid reduction of blood lactates and thus contributes to accelerated regeneration. |
| **Limitations** | none |
| **Summary** | For the study, blood lactate concentrations were measured in 10 basketball players subjected to standardized, intense, graduated exercise stress, each before and after a 30-minute VACUSPORT exposure. The average reduction was 87.5%, which significantly accelerated the athletes' recovery and thus their resumption of the next training session or competition. The study proves that VACUSPORT accelerates the recovery of athletes. |

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| **Reference No.** | 106 |
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| **Bibliographic Data** | Dong, H. H., B. H. Gao, H. Zhu et al.: The effects of lower limb intermittent negative pressure therapy on the skin microcirculation perfusion of quadriceps in male rowers. In: Chinese Journal of applied Physiology, 2019 (35; 126 – 129) [A.37] |
| **Quality of evidence** | 2 a |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The aim of this study is to investigate the effects of IVT on regeneration acceleration in high-performance sports. For this purpose, 14 (n=14) male rowers, all members of the national rowing squad, are recruited at the Institute of Kinesiology of Shanghai University of Sports and divided into an experimental group and a control group. The mean age is 23.71 years (+/- 2.04), height is 196.28 cm (+/- 4.02), weight is 98.17 (+/- 5.12). A four-week daily training was performed with a total volume of 676.4 km and a total time of 5,281 minutes, The intervention group received during this time 6 x VACUSPORT (VACUMED) for 20 minutes each, - 60 mbar, negative pressure : normal pressure ratio = 30 : 10 sec. The PeriFluxSystem 5000 laser Doppler blood flow meter (LDF) was used as test equipment to record blood flow in ml/min. This involves heating the tissue to 44 degrees as standard. The changes in the microcirculation of the tissue are directly reflected. In each case, the tests took place on the right quadriceps and included the average blood cell velocity (AVBC) and the concentration of movement blood cells (CMBC), which maps the microcirculation of blood perfusion (MBP) (MBP = CMBC x AVBC/100). Pre-exercise and intervention measurements showed no statistically significant differences in either group. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | After the training phase, the control group showed a reduction of 24.01% in MBP compared to 1.94% for the intervention group. AVBC also changed significantly in the intervention group after the training phase compared to the control group. The most important differences were in CMBC, which decreased by an average of 21.90% in the control group and increased by an average of 54.37% in the VACUSPORT group. The applications were well tolerated by all subjects, demonstrating that IVT with the VACUSPORT (VACUMED) device can exploit the reserve capacities of the microcirculation. The retrieval of muscular power is significantly better in the experimental group than in the control group after the four-week training period. |
| **Conclusions** | The improvement of microcirculation correlates positively with the restoration of physical fitness and performance. IVT with the VACUPSORT device improves the function of skin microcirculation, which inevitably improves blood flow in muscles and increases physical performance. VACUSPORT increases oxygen concentration and transport ability of nutrients in arteries and accelerates cell metabolism. This shortens recovery after training or competitions and improves the competitiveness of athletes. In conclusion, intermittent negative pressure therapy for the lower limbs can improve athletic performance after training or competition. The status of the microcirculation is measurably optimized (here using the quadriceps skin of athletes as an example), which promotes physical fitness and leads to a positive faster recovery. |
| **Limitations** | none |

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| **Summary** | In the study, 14 rowers of the Chinese national Olympic squad are exposed to four weeks of intensive training. 7 athletes will each receive 6 VACUSPORT applications during this time. In all athletes, the microcirculation (MBP), characterized by the average velocity of blood cells (AVBC) and the average concentration of moving blood cells (ACBC) are measured in parallel. After four weeks, a clear difference is seen: while MBP decreases significantly in the control group, it remains almost constant in the VACUSPORT group. In the case of CMBC, there is even an increase in the experimental group after four weeks, while it decreases in the control group. In conclusion, IVT for the lower limbs can improve men's rowing, and the microcirculation status of athletes' quadriceps skin indicates promotion of physical fitness and performance. The study proves that VACUSPORT can accelerate recovery after intense training- and thus contribute to better performance of athletes. |

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| **Reference No.** | 107 |
| **Bibliographic Data** | Pimenta, V.: Intermittent Vacuum Therapy. Lissabon 2021. In: https://sportaerztezeitung.com/rubriken/therapie/7527/intermittent-vacuum-therapy/ (28.12.2021) [A.40] |
| **Quality of evidence** | 2c |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | This study investigates the effect of VACUSPORT on muscle lesions in the rectus femoris muscle of the dominant leg of athletes. For this purpose, a group of 10 athletes was recruited over a period of 1.5 years, divided into 5 pairs each with a rupture of equal length (2.4 cm, 1.8 cm, 1.4 cm, 1.0 cm and 0.8 cm). In each pair, one athlete used Intermittent Vacuum Therapy (IVT) in addition to standard conservative care (followed by exercise under clinical conditions during the final recovery period) and the other did not. IVT was applied daily for 45 minutes with negative pressure up to -53 mbar. All tears were diagnosed and measured by ultrasound imaging at baseline and then at each of 7, 15, and 20 days. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Already after 7 days, a significantly better wound healing is shown in the IVT group than in the control group Pair 1 = 2.4 cm; IVT 1.3 cm / without IVT 2.0 cm. Pair 2 = 1.8 cm; IVT 1.0 cm / without IVT 1.4 cm. Pair 3 = 1.4 cm; IVT 0.7 cm / without IVT 1.1 cm. Pair 4 = 1.0 cm; IVT 0.4 cm / without IVT 0.6 cm. Pair 5 = 0.8 cm; IVT closed / without IVT 0.2 cm. After 15 days: Pair 1 = 2.4 cm; IVT 0.7 cm / without IVT 1.20 cm. Pair 2 = 1.8 cm; IVT 0.2 cm / without IVT 0.8 cm. Pair 3 = 1.4 cm; IVT closed / without IVT 0.5 cm. Pair 4 closed on both . Pair 5 closed in both. After 20 days, all participants in the IVT group had closed wounds; the wound from pair 1 without IVT was still 0.5 cm wide; from pair 2, 0.2 cm. All participants tolerated the applications well. |
| **Conclusions** | Incorporating IVT into muscle recovery shortened rehabilitation and return-to-play time compared to athletes in each other group. Strikingly, the greater the muscle injury and associated edema, the faster the wound healing acceleration. Post-traumatic conditions and wounds are not a contraindication for VACUSPORT. |
| **Limitations** | Not all bodies react in the same way to the same stimulus and the direct comparison of IVT / without IVT is certainly to be questioned with this small n. However, as an outcome consideration, the results provide an unambiguous result. |
| **Summary** | In a clinical setting, 2 x 5 athletes with comparable muscle tears between 2.4 and 0.8 cm were treated conservatively, with one group additionally treated daily with VACUSPORT. The respective width of the wound was measured by imaging immediately after injury and then on day 7,15 and 20. All athletes who received additional VACUSPORT showed significantly faster healing. The study shows that VACUPORT (VACUMED) can promote wound healing and shorten the rehabilitation time after muscle injuries. |

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| **Reference No.** | 110 |
| **Bibliographic Data** | Beyzadeoglu, T., K. Yilidirim: Intermittent Vacuum Therapy adter ACL Surgery. Istanbul, 2021. Teilveröffentlicht in: https://sportaerztezeitung.com/rubriken/therapie/7057/intermittent-vacuum-therapy-after-acl-surgery/ (28.12.2021) [A.42] |
| **Quality of evidence** | 2c |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Reconstruction of the anterior cruciate ligament (ACL) is one of the most common orthopedic surgeries worldwide (incidence approx. 60/100,000) and occurs mainly in athletes. The study considers 57 top athletes (n = 57) from elite soccer, basketball and volleyball, partly on national team level, who underwent ACL reconstruction. The duration and course of post-operative rehabilitation depend critically on pain from edema and swelling of soft tissues, which can delay effective physical therapy and resumption of training. The athlete cannot receive effective physical therapy and exercise until the edema is under control and the patient has become pain free. According to standard protocol, all patients received physiotherapy from day 3 after surgery. 28 of these athletes (group VM +) received additional applications of VACUMED 4 times a week from day 3 after surgery. To assess soft tissue edema and swelling, limb circumference was measured 15 cm proximal to the patella (PP), at the level of the middle of the patella (CP), and at the level of the pes anserinus attachment at the tibia (PA), where semitendinosus and/or gracilis tendon graft(s) were harvested. Measurements were taken before the start of the intervention on day 3 and on day 14. Intraarticular hemarthrosis and effusion did not affect the range of measurements. Baseline values had approximately equal circumferences in both groups. VM+ (n=28): PP 51, CP 47, PA 43. VM- (n=29): PP 50, CP 48, PA 44. |
| **Results** | The average results on day 14: VM+: PP 45 (-12%), CP 44 (-6%), PA 40 (-7%). VM-: PP 48 (-4%), CP 47 (- 2%), PA 43 (-2.8%). Overall, the VM+ group had an average reduction of -8.5% and the VM- group of -2.8%. Although the percentages for each group appear small, the average reduction in soft tissue swelling in the VM+ group (8.5%) was three times greater than in the VM- group. proving that IVT is an effective method for treating soft tissue edema and swelling . |
| **Overall Outcome** | In VM+ was measured after 14 days. Although the percentages for each group appear small, the average decrease in soft tissue swelling in the VM+ group (8.5%) was three times that in the VM- group, proving that IVT is an effective method for treating soft tissue edema and swelling . Considering that soft tissue edema, swelling and pain negatively affect physiotherapy and recovery, intermittent vacuum therapy should be considered for patients - especially elite athletes - after musculoskeletal injuries and/or surgery. |
| **Conclusions** | IVT is an effective method of treating soft tissue edema and swelling post-operatively. This is due to the lymphatic drainage enhancing effect of the treatment. Given that soft tissue edema, swelling, and pain negatively affect physical therapy and recovery, intermittent vacuum therapy can shorten rehabilitation and return to training (RTT) and play (RTP) for patients-particularly elite athletes-following musculoskeletal injuries and/or surgery. |
| **Limitations** | The study is not randomized but provides a clear outcome |
| **Summary** | 57 athletes who received ACL - reconstruction receive standard protocol according to physiotherapy from the 3rd day after the procedure. 28 participants receive additional 4 x weekly applications with VACUMED (VM+ group). On the 14th day after surgery, a threefold reduction of soft tissue edema is measured in the VM+ group compared to the group that did not receive VACUMED applications. This makes concomitant physiotherapy more effective and shortens RTT and RTP. The study proves that VACUMED can be used post-operatively, has a lymph drainage promoting effect and shortens the rehabilitation time. |

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| **Reference No.** | 111 |
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| **Bibliographic Data** | Hageman, D., H.J.P. Fokkenrood, B.A.C. Deursen et al.: Randoized controlled trial of Vacuum Therapy for Intermittent Claudication. In: Jouropean journal of vascular and edovascular surgery, 2019. [A.44] |
| **Quality of evidence** | 1b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The "gold standard" for intermittent claudication (IC) is standardized walking stretch training (SET = supervised exercise therapy). The aim of this controlled randomized trial is to investigate whether IVT with VACUMED is beneficial in addition to SET. For this purpose, 70 patients (n=70, all male, mean age 68, mean BMI 28) with stage II (Fontaine) pAVD were recruited who were willing to participate in 30 minutes of SET 2 to 3 times per week. Concomitant diseases in the form of hypertension, CHD, COPD, or renal insufficiency were tolerated. Patients with rest pain, ischemia, or hip or knee osteoarthritis were excluded. All patients received a standardized SET program over a 12-week period. Thirty-six patients were randomized to an intervention group with IVT treatment (-50 mbar negative pressure). In contrast, 34 patients received sham application with VACUMED (- 5mbar). The intervention was performed with 12 sessions within the first 6 weeks, 2 x weekly, 30 minutes. The primary endpoint was a change in maximal walking distance (MWD = maxiaml walking distance) and functional walking distance (FWD functional treadmill walking distance) on the treadmill. In addition, disease-specific quality of life was measured with the VascuQol questionnaire and generic quality of life with the EuroQol (Eq-5D). |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Of the 70 patients, 5 discontinued the program before the end of 12 weeks for reasons of lack of interest (3), myocardial infarction (1), and hip osteoarthritis (1). Both groups showed comparable MWD and FWD at all time points (P>0.05), with MWD and FWD increasing in both groups. In contrast, the VascuQol improved the quality of life of the intervention group in terms of pain perception, perceived disease symptoms, activity, sociality, and emotionality. |
| **Conclusions** | Standardized walking distance training (SET) is generally accepted as first-line treatment. If, according to the study, VACUMED is applied adjuvantly in the first six weeks, this does not bring any further advantages with regard to the extension of the walking distance after 6 or 12 weeks, but it does with regard to the quality of life and the perception of pain. |
| **Limitations** | VACUMED was only applied during the first six weeks and not over the entire duration of the study. The increase in walking distance after six or twelve weeks was not compared with the results of other SET studies. The exclusion criteria (rest pain, ischemia, arthrosis) reduced the study group. |
| **Summary** | In an RCT, 70 patients receive 12 weeks of standard ambulation training (SET) and IVT with the VACUMED. In 34 patients the VACUMED application was only for sham with - 5 mbar, in the others with up to -54 mbar. There were no differences with regard to walking distance. Differences in favor of the intervention group were only found in the area of quality of life. The study shows that VACUMED can increase the quality of life of pAVK II - patients. |

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| **Reference No.** | 112 |
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| **Bibliographic Data** | Yespenbetova, M.Zh., N.S. Izatullayeva, A.Kh. Khassenova et al.: The analysis of efficiency of application of interval vacuum therapy on the device VACUMED in patients with diabetic foot infections. Semey, 2016 (Unveröffentlicht) [A.45] |
| **Quality of evidence** | 2 b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Diabetes melitus (DM) has a prevalence of approximately 10% in developed countries and leads to the development of diabetic foot syndrome (DFS) in approximately 15% of sufferers, resulting in amputation in approximately 18% of DFS cases. The aim of the study at the Faculty of Medicine, Kazakhstan State University, Semey, was to evaluate the efficacy of IVT with the VACUMED in patients with diabetic foot infections. The study included 82 patients (n=82, of which 37% - men, 63% - women) with DFS. The mean age of the patients was 60.1±12.6 years. Inclusion criteria were made after clinical examination and verification of diagnosis according to the criteria of the American Diabetes Association (DIAINF Study Group). According to these criteria, 56% of patients had neuropathic DFS, 18% had ischemic DF, and 26% had neuroischemic DFD. Duration of disease was 1-5 years in 4%, 5-10 years in 6%, and >10 years in 90%. Patients received 10 sessions each, 20 minutes, -30 to - 40 mm Hg at intervals of 2 to 4 days. Parameters determined were lower extremity macrocirculation (US Dopler), arterial pressure, and pain sensation along the standard rating scale (NRS, baseline before intervention 8.8). |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | A reduction in stenosis from 58% to 93% was measured. Lower extremity pain, the measurement of which was an important component in assessing the efficacy of procedures according to the study, decreased by an average of 3.2 points in the first 5 days (5.6) and by another 3.5 points after 10 sessions, giving an average reduction in pain of 76.1%. A decrease in feelings of pressure and heaviness in the legs was also noted. Positive effects were also seen in blood pressure. The average values before intervention: 15 +/- 12 systolic, 95 +/- 5 diastolic; after intervention: 120 +/-10; 85 +/- 5. Also, epithelialization was noted in the ulcerations, which were shown to be resistant to other forms of complex therapies in the initial history. |
| **Conclusions** | The effectiveness of blood flow promotion of IVT with the VACUMED device is evident in patients with DFS and can reduce the number of amputations. |
| **Limitations** | The comparison against the historical collective is to be evaluated as an outcome or pilot study. |
| **Summary** | In the study, 82 patients with an average age of 60.1 years and diagnosed DFS are treated with VACUMD 10 times each. Significant results are shown with regard to blood pressure reduction, initiation of epithelialization and reduction of pain sensation. The study demonstrates that VACUMED promotes blood flow and microcirculation and can reduce pain and initiate healing of tissue damage in DFS. |

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| **Reference No.** | 113 |
|---|---|
| **Bibliographic Data** | Afzelius, P., S. Molsted, L. Tarnow : Intermittent vacuum treatment with VacuMed does not improve peripheral artery disease or walking capacity in patients with intermittent claudication. In: Scandinavian Journal of Clinical and Laboratory Investigation, 2018 (78:6, 456-463) [A.61] |
| **Quality of evidence** | 1b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | In a prospective, randomized, open-label and blinded endpoint study (PROBE) at the Department of Clinical Physiology, Nordsjaellands Hospital, Hillerød, Denmark, the influence of VACUMED in patients with mild or moderate pAVD is investigated. For this purpose, 48 (n=48) patients with an ABI <0.9 were randomized to a control and an intervention group. Characteristics of the intervention group: n=23; mean age 69 +/-7, BMI 28 +/- 5, systolic BP brachial 148 +/- 20, diastolic 81 +/- 10, diabetes 10, peripheral neuropathy 5); control group: n=25; mean age 70 +/-9 BMI 29 +/- 3, systolic BP brachial 139 +/- 20, diastolic 78 +/- 9, diabetes 5, peripheral neuropathy 2. Exclusion criteria: ABI <50 mmHg, toe BP <30 mmHg, edema (complicating distal BP measurement), and acute lower extremity bleeding. In all patients, lifestyle modification was agreed upon as first-line therapy in treatment by a physician according to the Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases (Aboyans V. et al, 2017), characterized by abstention from smoking, dietary adjustment toward a low-fat diet, and daily gait training to the pain point. The intervention group also received 40 minutes of VACUMED 3 times a week for 6 weeks, -25 to - 37 mmHg , 7 sec. Negative pressure / 9 sec. normal pressure. Primary endpoint: measurement of ABI before and after 6 weeks, blinded. Secondary endpoints were ankle and big toe blood pressure, walking ability, symptoms of intermittent claudication, physical activity, adverse events, and general and disease-specific self-rated health. All patients tolerated VACUMED applications well. There was one dropout in the IVT group due to geographic distance . |
| **Results**<br>· **Overall Outcome**<br>· **Performance**<br>· **Benefits** | No significant differences were found in ABI or blood pressure. The walking distance test remained without differences between the groups. The level of objectively tested physical activity could only be tested in 18 and 19 patients of the IVT and C groups, respectively, because of problems with the technical equipment; however, it remained approximately the same there as well. Changes in self-assessed health status also showed no differences between the IVT and C groups, whereas self-assessed walking distance tended to decrease in the C group and increase in the IVT group. This was contradicted by the actual recorded objective physical activity. |
| **Conclusions** | In mild to moderate pAVD, no effects are shown by the complementary use of VACUMED to standardized daily gait training combined with supervised lifestyle and dietary changes (first-line therapy). |
| **Limitations** | Both groups were initially intervened by lifestyle modification and walking distance training, which leads to the measured results by itsself. Since a majority of the mostly elderly patients are not eligible for first-line therapy from a psychosocial and/or physiological point of view, an investigation of lifestyle modification plus walking distance training vs. IVT would also be desirable. |
| **Summary** | In one study, 48 patients with mild to moderate PAOD were recruited and underwent supervised lifestyle and dietary changes and daily walking stretch training. 23 patients also received VACUMED application 3 times per week for six weeks. VACUMED was found to have no effect on ABI, blood pressure at the ankle and big toe, or self-assessed additional improvement in quality of life, complementary to the initial intervention. The study shows that VACUMED applications are well tolerated by patients with mild and moderate PAOD. |

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| **Reference No.** | 114 |
|---|---|
| **Bibliographic Data** | Klinik Fallingbostel: Unterdruck bringt das Blut in Schwung. Schaufensterkrankheit. Patienteninformation. 2005. Dokumentennummer A.46 |
| **Quality of evidence** | 5 |
| **Study description** | |
| · **Device** | |
| · **Objective** | |
| · **Endpoint** | |
| · **Statistical measure** | In a patient information, the chief physician, Dr. Schink, reports on the use of VACUMED at the Fallingbostel Clinic for pAVK on more than 100 patients. |
| · **Patient Population** | |
| · **Number** | |
| · **Indications** | |
| · **Contraindications** | |
| **Results** | |
| · **Overall Outcome** | |
| · **Costs** | |
| · **Adverse Events** | "In most cases, there was a significant improvement in symptoms." |
| · **Performance** | |
| · **Benefits** | |
| **Conclusions** | VACUMED is indicated for PAD and shortened walking distances. |
| **Limitations** | VACUMED is used complementary to walking stretch training and in advanced stadiums complementary to vascular surgery procedures. |
| **Summary** | A patient information describes the use and effect of VACUMED as a complementary therapy component in the treatment of PAD. |

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| **Reference No.** | 115 |
|---|---|
| **Bibliographic Data** | Kreft-Weyergans, K.: Intermittierende Untrerdrucktherapie. Neue Perspektiven bei Gefäßerkrankungen. In.: VASOMED, 2003 (5). Dokumentennummer A.47 |
| **Quality of evidence** | 5 |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Report in the journal of the German Society of Phlebology about the first presentation of the VACUMED device, which was still new at that time, at a symposium with reference to the already confirmed indications: Thrombangitis obliterans, pAVK, venous ulcerations. Also relief in edema therapy (complementary to manual lymphatic drainage). Also already indications of increase in general well-being. |
| **Conclusions** | VACUMED has arrived in phlebology. |
| **Limitations** | N/A |
| **Summary** | Description of the VACUMED device, its origin and use (indications) in vascular medicine, here in phlebology. |

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| **Reference No.** | 116 |
|---|---|
| **Bibliographic Data** | Mohammad-Yar, A.: Intermittierende Unterdrucktherapie. In: Diabetes & Technologie. Arbeitsgemeinschaft der Deutschen Diabetes Gesellschaft. Ulm, 2013 (1, 15978) [A.48] |
| **Quality of evidence** | 5 |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Description of the VACUMED device and its use at the Heart and Diabetes Center NRW, Ruhr-University Bochum, Bad Qeynhausen as an adjunct to conservative treatment of Claudiaction Intermittens. Also summary of the studies performed until then (metastudy). Description of the physical effect of IVT in the form of a strong capillary dilatation and capillarization and its pyhsiological outcome in the form of blood flow promotion of the periphery and musculature (micro- and macroperfusion) in the lower extremities, pain relief, extension of walking distance, reduction of heart rate, reduction of diastolic blood pressure. Reference to contraindications: fresh phlebothrombosis up to 8 weeks old, infected wounds, inguinal hernia, pregnancy abdominal wall scar hernia. Verwesi to the fact that CHD is not a contraindication. Indication of increase in well-being and quality of life. |
| **Results**<br>· **Overall Outcome**<br>· **Costs** | At the HDZ, VACUMED makes a decisive contribution to positively influencing painful vasoconstrictions of the exptremities (pAVK) by improving the oxygen supply of the undersupplied tissue, which leads to rapid pain relief up to freedom from pain. Chronic wounds heal and the threat of amputation can be prevented. |
| **Conclusions** | A positive effect of VACUMED in the indication PAD II to IV has been comprehensively confirmed. |
| **Limitations** | VACUMED is used in addition to daily walking distance training and to address risk factors such as high cholesterol and smoking. |
| **Summary** | VACUMED leads to strong rhythmic capillary dilation and capillarization, improving micro- and macroperfusion, which can reduce severity, increase walking distance and prevent amputation in patients with PAOD. In combination with walking distance training and risk reduction (cholesterol, smoking) the results become sustainable. |

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| **Reference No.** | 117 |
|---|---|
| **Bibliographic Data** | Linz, E.: Die Vakuum-Alternative. Neue Perspektiven in der Beahndlung von Beinleiden und chronb. Wunden. In: Rechtsdepeche für das Gesundheitswesen. Köln, 2016 (4). [A.49] |
| **Quality of evidence** | 5 |
| **Study description** | |
| · **Device** | |
| · **Objective** | The angiologist and phlebologist, E. Linz, reports in the professional journal of the ICW (Initiative Chronische Wunde) about the use of two VACUMED devices in his practice and describes the physical rhythmic vascular dilatation, which physiologically leads to a better blood circulation in the periphery and to an increase in venous and lymphatic outflow. It confirms good efficacy in decongestion of venous and lymphatic edema and measurable improvement in blood flow, pain reduction and prolongation of the walking distance in PAOD. There are also new perspectives in the treatment of pregangrenous ischemia and arteriosclerotic erectile dysfunction. |
| · **Endpoint** | |
| · **Statistical measure** | |
| · **Patient Population** | |
| · **Number** | |
| · **Indications** | |
| · **Contraindications** | |
| **Results** | |
| · **Overall Outcome** | |
| · **Costs** | After ten years of use in angiological and phlebolgical special practice, a positive effect in the above-mentioned indications as well as a positive patient response is attested. |
| · **Adverse Events** | |
| · **Performance** | |
| · **Benefits** | |
| **Conclusions** | VACUMED offers positive benefits in angiological circulatory disorders (including ischemia) as well as phlebological indications (CVI and venous ulcers). New perspectives are emerging for arteriosclerosis-related erectile dysfunction. |
| **Limitations** | N/A |
| **Summary** | A practical report from angiology and phlebology, which after ten years of use of two VACUMED devices confirms the indications in connection with a pAVK and CVI and also evaluates the use of IVT as "...new perspective...in arteriosclerotic erectile dysfunction". |

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| **Reference No.** | 118 |
|---|---|
| **Bibliographic Data** | Ruyters, G., H.U. Hoffmann: The German Space Life Sciences Program- 4th European Congress on Medicine in Spece and Extreme Environments. Vortrag der DLR. Berlin, 2007 [A.50] |
| **Quality of evidence** | 5 |
| **Study description** | |
| · **Device** | |
| · **Objective** | |
| · **Endpoint** | The presentation also describes important spin-offs under the heading "ImprovingHealth", citing the Lower Body Negative Pressure Device (LBNP) project. Purpose: Cardiovascular stimulation. Scientificdeveloper:Dr.Baisch, DLR Inst. for Aerospace Medicine, Cologne. Space project:STS-90 NEUROLAB. Company:Weyergans High CareAG, Düren. Commercial device:Vacumed. Application:Treatment and prophylaxis of peripheral circulatory disorders and cellulitis. |
| · **Statistical measure** | |
| · **Patient Population** | |
| · **Number** | |
| · **Indications** | |
| · **Contraindications** | |
| **Results** | |
| · **Overall Outcome** | |
| · **Costs** | VACUMED was developed by the German Aerospace Center (DLR) and built by Weyergans. The original purpose was treatment and prophylaxis of peripheral circulation disorders and "cellulitis". |
| · **Adverse Events** | |
| · **Performance** | |
| · **Benefits** | |
| **Conclusions** | Experiences and technologies from space medicine are adapted for use on earth |
| **Limitations** | N/A |
| **Summary** | VACUMED was developed for the treatment and prophylaxis of peripheral circulatory disorders and cellulitis by DLR as a space project (STS-90 NEUROLAB) and built by Weyergans. |

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| **Reference No.** | 119 |
|---|---|
| **Bibliographic Data** | Amninjara, S.: Investigation of Vacustyler using for patients with venous and areterial blood circulation distrubance. In: Anwendungsbeobachtung. Riga, 2003 [A.51] |
| **Quality of evidence** | 2 c |
| **Study description** | |
| · **Device** | |
| · **Objective** | |
| · **Endpoint** | 23 subjects (n=23), 12 with PAOD and 13 with CVI. All suffer from pain at rest, several from paresthesia, skin lesions and ulcerations. All patients are multimorbid; one additionally suffers from an abdominal aneurysm; two patients have already had a major amputation. All patients are on medication. The patients received up to 2 applications of Vacustyler (= non-medicated version of VACUMED) daily for the first five days and then one application daily for each of the next ten days. The negative pressure was successively increased. |
| · **Statistical measure** | |
| · **Patient Population** | |
| · **Number** | |
| · **Indications** | |
| · **Contraindications** | |
| **Results** | |
| · **Overall Outcome** | |
| · **Costs** | All patients tolerated the applications well and reported pain reduction and warmer feet during application, which lasted for 2 to 4 hours each afterwards. All patients reported a significant decrease in pain; none had complete disappearance of the aches and pains. In patients with ulcerations, there was clearly visible epitelization after three to four applications. One patient who was already scheduled for amputation was able to avoid it. |
| · **Adverse Events** | |
| · **Performance** | |
| · **Benefits** | |
| **Conclusions** | IVT improves blood circulation, resolves vascular spasm, and stimulates collateral perfusion when the great vessels are not working properly. |
| **Limitations** | |
| **Summary** | An observational study from Latvia shows that IVT significantly reduces pain and revascularizes ulcerations in 23 angiological and phlebological pain patients. |

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| **Reference No.** | 120 |
|---|---|
| **Bibliographic Data** | Lauxen, W.: Anwednungsbeobachtung und Erfahrungsbericht über einen Patienten Z.n. Vorßamputation. Aschaffenburg, 2004 [A.52] |
| **Quality of evidence** | 3b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Patient, male, pAVK bilateral, lower leg type, after forefoot amputation li.1992 because of thrombendangitis obliterans. In June 2002, the patient is 47 years old; the forefoot is infected; previous ambulatory treatments show no effect anymore. An inpatient stay with systemic antibiotics and administration of Prostavasin infusions as well as regular local wound treatment brings only temporary slight improvement. Patient is on a hopeless path of incapacity to work, severe restriction of mobility and associated psychological and physical stress. After discharge, the patient is cared for over two years in a medical supply store with an affiliated wound center, where he receives IVT with Vacustyler (=precursor VACUMED) several times a week. The treatments were documented both in writing (including technical settings) and photographically. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Pain: Already after the first 10 applications, the patient reported significantly less pain and was able to reduce painkillers. After the 20th application, pain medication is no longer required. The patient is completely pain-free at the time of the report. Sweating: very heavy at start of treatment; after 15 to 20 applications noticeable reduction, after 80 applications no more sweating. Walking distance: initial 300 bsi 500 m to pain; after 10 LBNP applications already > 1,000 m; after 30 treatments > 2 km; from July 2003 > 5 km; May 2004 > 15 km on uneven terrain without any complaints. Skin appearance: previously severe eczema on both feet; after 50 applications, skin defects on both sides completely healed; also improvement of skin appearance on face and arms. Wound healing: Onset of wound healing already noticeable during the first ten applications. At the end of the treatment series at report, the wounds are completely healed. |
| **Conclusions** | IVT helps to avoid further amputations in out of treatment pAVK IV - patients, to restore the quality of life and to avoid further hospitalizations / disablements in a cost effective way. |
| **Limitations** | N/A |
| **Summary** | A recurrent PAOD patient with forefoot amputation who has already undergone a full course of treatment is at risk of further amputation, hospiatlization, disability and incapacitation. He receives intermittent LBNP over a two-year period and is fully recovered. IVT helps to revascularize when all other therapies have been exhausted. |

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| **Reference No.** | 121 |
|---|---|
| **Bibliographic Data** | Tschöpe, D.: Intermittierende Vakuumtherpaie zur Verbesserung der periphere Durchblutungssituation bei pAVK. Abschlussbericht zur klinischen Prüfung nach Abbruch der Studie. Bad Oeynhausen, 2017. [A.53] |
| **Quality of evidence** | 1 b |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The study at the HDZ (Rhein-Ruhr University, Bochum) examines the question whether IVT leads to an improvement of peripheral perfusion in DM patients with pAVK (stage II - IV) and wants to randomize patients with and without wound involvement into two treatment groups -50 mbar and - 10 mbar. The oxygen perfusion in the target tissue (TcpO2) should be < 25 mbar, since the patients are then already considered as out of treatment and palliative and, according to the ethics committee, further interventions no longer offer any prospect of improvement. Target n = 50. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | First patient in: 15.01.2015; Last patient out: 08.02.2016; Reported study termination: 29.07.2017, because "...due to significantly improved intervention possibilities via angioplasty and vascular surgery" not enough patients could be recruited. In four already enrolled and randomized patients, the main evaluation parameter, TcpO2, showed improvement in six measurements and deterioration in two measurements. On average, perfusion improved by 750% (although with a large standard deviation of +/- 1074%). If two measurements with an improvement of more than 1000% are not taken into account, the average improvement in perfusion is 201 +/- 131%. In the -10 mbar group, one TcpO2 measurement is relevant to the study, since a significant improvement also occurred there (183% in relation to the value at study inclusion). No adverse reportable events occurred. |
| **Conclusions** | VACUMED can increase oxygen delivery in palliative pAVK patients with a TcpO2 of < 25 mbar in the target tissue. |
| **Limitations** | The study, which in principle requires a palliative approach in order not to relativize the measurement of the effects of VACUMED by other interventions, was unsuccessful to recruit due to the egg exclusion criteria, because in the course of the study interventional options at the site "...improved" and thus competed with the study, which would be "...unethical" (sic!). |
| **Summary** | A study in out-of-treatment and palliative DM patients with pAVK studies II to IV and a TcpO2 of < 25 mbar shows that interventrion with VACUMED can increase oxygen saturation by 750%. Even lower negative pressures can have effects on O2 supply in extremely underperfused patients. |

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| **Reference No.** | 122 |
|---|---|
| **Bibliographic Data** | Anatoljewa, G.O.: Use of Interval Vacuum Therapy with VACUMED in the complex treatment of woman with chronic inflammatory diseases of the pelvic bodies and infertility. Kaliningrad, 2015 [A.54] |
| **Quality of evidence** | 2a |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Pelvic organ inflammatory diseases occupy the first place in the structure of gynecological morbidity and are the most frequent cause of impaired menstrual, reproductive and sexual functions in women. According to the literature, ovarian hypofunction is observed in almost 90% of patients with chronic pelvic inflammatory diseases. This is due to the development of dystrophic processes in the uterine appendages due to a lack of blood supply and the development of adhesive changes. Physical factors remain the leading component in the complex of pathogenetically based therapeutic measures. Against this background, the purpose of the study is to verify the effectiveness of IVT with VACUMED in the complex treatment of women with chronic inflammatory diseases of pelvic organs and infertility. In particular, to measure the dynamics of changes in blood flow in the main vessels of the pelvis (in the uterine and ovarian arteries) in women with chronic pelvic organ diseases and infertility before and after 10 times of VACUMED application. To measure, by ultrasound monitoring of follicles, the recovery of ovulatory cycles in women with chronic pelvic organ disease and infertility before and after 10 sessions of VACUMED; in parallel, to measure the severity of premenstrual syndrome on a pain scale in women with chronic pelvic organ disease and premenstrual syndrome before and after 10 sessions of VACUMED. Included were 20 female patients (n=20) with chronic pelvic organ diseases, infertility (chronic metroendometritis), with 4 patients showing chronic salpingo-ophoritis (unilateral and bilateral), 4 patients showing primary infertility, 4 patients showing secondary infertility, 5 patients showing premenstrual syndrome. Before treatment and one week after the tenth VACUMED application, all PAtients underwent ultrasound Doppler examination. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | In all patients, after ten applications of VACUMED, blood flow in the vessels of the uterus and ovaries improved.this contributes to the positive dynamics of the treatment of infertility and chronic inflammatory diseases of the pelvic organs. In addition, patients noticed the restoration of ovulation cycles (ultrasound monitoring of follicles), a decrease in the severity of premenstrual syndrome (rating on a pain scale). One patient had a desired pregnancy. |
| **Conclusions** | IVT with the VACUMED device in patients with chronic pelvic inflammatory diseases and infertility leads to the restoration of ovulatory menstrual cycles, reduction of the severity of premenstrual syndrome and may contribute to the onset of a desired pregnancy. The data obtained suggest that the use of this method is promising in the complex treatment of infertility and chronic pelvic inflammatory diseases. |
| **Limitations** | N/A |
| **Summary** | VACUMED in gynecology / urogynecology in chronic metroendometritis, inflammatory diseases of pelvic organs and PMS has a positive effect on the blood flow in the vessels, which promotes the regularity of ovulation cycles, reduces pain associated with menstruation and positively affects the dynamics of fertility. |

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| **Reference No.** | 123 |
|---|---|
| **Bibliographic Data** | Campisi, C.: Stellungnahme zur Anwendung der IVT mit dem VACUMED in der Behandlung von Lymphödemen. Schriftwechsel, 2008 [A.53] |
| **Quality of evidence** | 5 |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The author, Corradino Campisi, is President of the International Society of Lymphology and an internationally renowned author, speaker and COL. In his private practice, in addition to his chair at the Faculty of Medicine of the University of Genoa, Italy, he operates two VACUMED devices that he uses on patients with lymphedema. He was confronted with the question whether, in his experience, IVT with the VACUMED is indicated in lymphedema and which technical parameters are applied in his practice. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | At the time of the survey, approximately 2,000 lymphedema patients had already been treated with VACUMED in the practice. The success rate is 90%. The optimal duration of the negative pressure phases is 21 seconds to 7 seconds of athmospheric pressure at -35 to - 40 mabr. The duration of a session in the practice is 20 minutes and patients are given an average of 12 sessions within two weeks. |
| **Conclusions** | VACUMED is effective in relieving lymphedema. It increases the return flow of lymph from the periphery to the interior and increases the total flow in the lymphatic system. |
| **Limitations** | N/A |
| **Summary** | In a medical lymphology specialty practice, over 2,000 patients with lymphedema have been successfully treated with approximately 90% success, with 21 seconds of negative pressure (vascular dilatation; infiltration phase) versus 7 seconds of normal pressure (compression phase) as the optimal technical setting. The shift of the excess lymphatic load proceeds from the periphery to the interior and then leads to an increase in the total flow. VACUMED is indicated as a method for the treatment of lymphedema. |

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| **Reference No.** | 124 |
|---|---|
| **Bibliographic Data** | Lucas, Leonardo: Report of one year use of VACUMED in Advanced Pain- and Rehabilitation Centre. Rio de Janeiro, 2020 [A.56] |
| **Quality of evidence** | 2 c (Outcome research) |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | In the Advanced Care Institute of Wounds (Instituto de Cuidados Avançados de Feridas, ICAF, Niteroi, Brazil), in collaboration with the Advanced Pain- and Rehabilitation Centre, IDRA, Rio de Janeiro, fifteen patients (n=15) with an average age of 57.6 years (28-96), 3 male and 12 female, 76% diabetic, with vascular pathologies are treated with VACUMED. Two of the patients with pAVK show claudication intermittens, two patients Z.n. laser saphenous endoablation, two with chronic lymphedema (one of them with resection of neoplasm with lymph node dissection in groin; one with lymphangitis), nine patients with chronic wounds on lower limbs. The aim of the study is to investigate the effect of VACUMED on vascular disease and pain. |
| **Results** | Acceleration of healing of acute and chronic wounds as well as improvement of the quality of the wound surrounding skin was observed and documented. The quality of the wound surrounding skin improved. Lymphedema/lymphangitis showed a significant decrease in lower limb edema. Pain management showed a reduction in wound-related pain. There were also reports of decreased joint pain in elderly patients and in a patient with fibromyalgia. Postoperative edema with induration in the topography of surgical incisions also improved. A prolongation of the walking distance was measured in the claudication patients. |
| **Conclusions** | VACUMED application is indicated in vascular medicine for use in a variety of angiological, phlebological or lymphologic indications. |
| **Limitations** | N/A |
| **Summary** | In an application observation at a pain and vascular rehabilitation clinic, VACUMED was successfully applied to 15 pain patients with typical angiological, phlebological and lymphatic vascular pathologies. There were initiations or acceleration of wound healing, reduction of edema volumes, extension of walking distance and reduction of pain. |

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| **Reference No.** | 125 |
|---|---|
| **Bibliographic Data** | Streminski, A.: Behandlungsbeobachtung unter Einsatz des VACUMEDim Zeitraum März bis Juli 2001 im Gefäßmediznischen Zentrum Köln. 2001 |
| **Quality of evidence** | 5 |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | In the Vascular Center at Rudolfplatz, Cologne, 10 patients (n=10) with pAVK stage IIb and clinical diagnosis of peripheral microcirculatory disturbances of the feet3 were treated with VACUMED. After thorough anamnesis, detection was performed with acral pulsation measurement at the toe and TcpO2 measurement. Each patient received 6 sessions, 20 minutes, -40 to -50 mmHg, at intervals of 2 to 4 days . |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Measurements were taken at each session immediately before treatment, during treatment, and approximately 30 minutes after treatment. There wasan average increase in O2 saturation compared with the reference value before treatment of 14% during treatment and 8% 30 minutes after treatment. Acral pulsation increased significantly with an increase in negative pressure. 7 of the 10 patients treated reported a subjective improvement in their symptoms. |
| **Conclusions** | According to the results of the observational study, the VACUMED device is indicated for peripheral microcirculatory disorders, e.g. diabetes, angiopathy, Raynaud's disease or thrombangitis obliterans. |
| **Limitations** | Indication in AVK is obvious based on the results, but would need to be confirmed in a larger patient group over a longer treatment period. The therapy also seems to be interesting for the above mentioned indications, especially in combination with simultaneous oxygen and/or infusion therapy, |
| **Summary** | In an application observation, ten patients with pAVK IIb and microcirculatory disturbance in the feet showed an improvement of the acral pulsation and an increase of the TcpO2. |

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| **Reference No.** | 126 |
|---|---|
| **Bibliographic Data** | Vincze, J.: Explanation of the release of NO by endothelial stimulation by VACUMED. Budapest, 2018 [A.58] |
| **Quality of evidence** | 5 |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | Nitrogen monoxide (NO) plays a significant role in vasodilation and is considered an important factor in the consideration of general health (see Nobel Prize in Medicine 1998). NO is regularly produced in the endothelia of the vessels, with both biochemical and mechanical processes playing a role. The present consideration biophysiologically explains whether a release of NO is provoked due to the shear forces initiated on the endothelium of vessels during IVT (VACUMED) applications. |
| **Results** | From a biophysiological point of view, the intermittent application of negative pressure to vessels initiates mechanisms similar to those found in nature. Against this background, IVT induced release of NO is neither aberrant nor excluded. |
| **Limitations** | Since NO is extremely volatile, it cannot be technically measured as a gas in the vessel or as a blood gas in practice. |
| **Summary** | See study description |

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| **Reference No.** | 127 |
|---|---|
| **Bibliographic Data** | Mijatovic, D., A. Gojevic, Z. Fiolic: Vincze, J.: Expert report on the evaluation and review of the device VACUMED (#04195279). Zagreb, 2020 [A.59] |
| **Quality of evidence** | 5 |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | The Clinical Hospital Zagreb, Salata (largest state hospital in Croatia) is conducting an evaluation of the VACUMED device for Intermittent Vacuum Therapy in vascular patients in the Day Surgery Clinic in the Surgical Clinics based on the General Rules of Procedure for the Validation of Medical Devices. It is explained that Chronic wounds are a major public health problem in all western countries, including Croatia. The most common are diabetic feet, venous hypostatic ulcers and arterial ischemic ulcers without the possibility of vascular reconstruction. In recent years, some progress has been made toward better use of vacuum assisted closure (VAC), an occlusive negative pressure pass. However, this method unfortunately requires hospitalization of patients and additional coil material, sponges, negative pressure tubing and other consumables each time the VAC system is changed. The IVT / LBVD (Low Body Vacuum Device) VACUMED works similarly to the VAC system except that IVT VACUMED applies negative pressure to the entire lower body rather than just the treated wound. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | The expert commission submits that there are a number of advantages with regard to VACUMED: no hospitalization of the patient is required. No expensive disposable sponges and tubes are needed, a simple dressing is sufficient. After three months of use in patients with chronic wounds and peripheral occlusive diseases, it was found that administration of Vacumed at intervals of 2-3 times a week for about half an hour after treatment has a very beneficial effect on patients with the above diseases. It leads to prolongation of walking distance in patients with peripheral arterial disease, discontinuation or significant reduction of rest pain in the same group of patients. This leads to a significant reduction in pain in patients with chronic wounds, as well as a significant reduction in pain in dressing and toileting wounds, which can be most important because these patients often have wounds that last months, sometimes years, and require proper dressing, toileting, and necrectomy. Many patients require general anesthesia for this. When using VACUMED, general anesthesia is not required to treat necrectomies and toilet wounds. After several Vacumed treatments, most of our patients with chronic wounds had healthy granulation and some epithelialization. |
| **Conclusions** | VACUMED is suitable for cost-effective use in vascular medicine for pAVK and has the advantage that it can be applied on an outpatient basis. |
| **Limitations** | VACUMED was used in a relatively small number of patients (about 20) within a limited time interval of several months, so the above results are not from scientific work, but from a clinical impression. |
| **Summary** | VACUMED is an integral part of the therapy offer in the vascular medicine department of the largest hospital in Croatia, as it offers therapeutic benefits and, compared to VAC therapy, is significantly less expensive, less burdensome for the patient and can be administered on an outpatient basis. |

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| **Reference No.** | 128 |
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| **Bibliographic Data** | Wiecha, S., M. Jarocka, P. Wisniowski et al.: The efficacy of intermittent pneumatic compression and negative pressure therapy on muscle function, soreness and serum indices of muscle damage: a randomized controlled trial. In: BMC Sports Science, Medicine and Rehabilitation, 2021 (13:144) |
| **Quality of evidence** | 1 c |
| **Study description**<br>· **Device**<br>· **Objective**<br>· **Endpoint**<br>· **Statistical measure**<br>· **Patient Population**<br>· **Number**<br>· **Indications**<br>· **Contraindications** | This study investigates whether intermittent pneumatic compression (IPC) and intermittent negative pressure (INP with the VACUSPORT device) have an attenuating effect on the muscle-damaging effects (DOMS) of eccentric training. Here, 45 healthy men (n=45) were recruited to complete a workout of 100 drop jumps. One hour after exercise and then at each of 24 and 48 hours, participants were randomized to receive a 30-min session of intermittent pneumatic compression (IPC, n=15, 80 mmHg) or intermittent negative pressure (INP, n=15; short intervals to 10 sec max between -24.7 and -36.7 mmHg) or sham treatment (microcurrent, PT, n=15). After each session, creatine kinase (CK), lactate dehydrogenase (LDH), isokinetic muscle strength, pain, and active flexion of the knee joint were measured. |
| **Results**<br>· **Overall Outcome**<br>· **Costs**<br>· **Adverse Events**<br>· **Performance**<br>· **Benefits** | Neither biochemical nor functional significant differences were observed between the groups. However, there were significant differences within groups in terms of muscle soreness, CK and LDH activity, reduction in muscle strength, and range of active knee flexion. All participants tolerated the interventions well. There were no intolerances and no dropouts. |
| **Conclusions** | In this study, no significant differences in biochemical or functional markers were measured after intense muscle-damaging extentric exercise between groups of 15 subjects each who received compression therapy or IVT or sham treatment (microcurrent) one hour after exercise and then at 24- and 48-hours each. |
| **Limitations** | N/A |
| **Summary** | Wiecha et al. 2021 investigated whether intermittent pneumatic compression (IPC) and intermittent negative pressure (INP with the VACUSPORT device) have an attenuating effect on the muscle-damaging effects (DOMS) of eccentric training. No significant differences in biochemical or functional markers were measured after intense muscle-damaging extentric exercise between groups of 15 subjects each who received compression therapy or IVT or sham treatment (microcurrent) one hour after exercise and then at 24- and 48-hours each. |