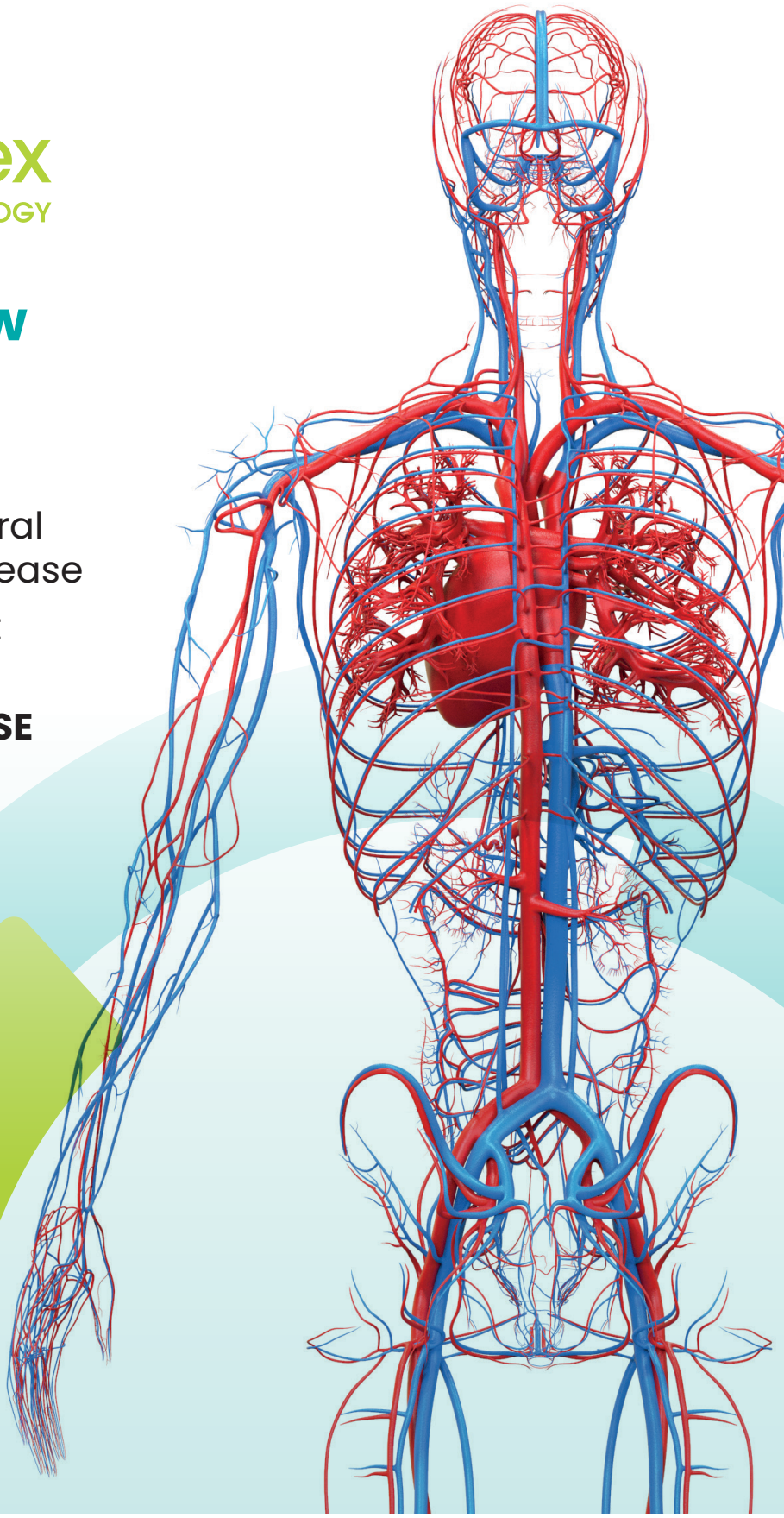
VADOplex® by OPED
VASCULAR IMPULSE TECHNOLOGY

Clinical review Studies and publications

Treatment of Peripheral Arterial Occlusive Disease

Wound Management

with
INTERMITTENT IMPULSE COMPRESSION (IIC)



OPED
Keeps you going.

Studies showing effectiveness of IIC in peripheral arterial occlusive disease

Physiological priciples of intermittent impulse compression and its effect on tissue prefusion

Gardner, A. M., & Fox, R. H. (1992).
The venous foot pump: influence on tissue perfusion and prevention of venous thrombosis. Annals of the Rheumatic Diseases, 51(10), 1173–1178. https://doi.org/10.1136/ard.51.10.1173

Device: **A-V Impulse System™**

The venous foot pump

A single compression of the venous foot plexus pumps between 20 and 30 ml of blood towards the heart. This pumping action is activated by simple weight bearing, when the arch of the foot flattens and the venous plexus is compressed. This happens without any involvment of the muscles. Thus, the so-called venous foot pump can be naturally activated by walking or artificially by pneumatic impulses on the sole of the foot.

Enhanced blood flow, improved tissue perfusion

It was shown that the artificial stimulation of the venous foot pump increases the blood flow in lower limbs (among others in posterior tibial vessels and the popliteal artery), leading to tissue hyperaemia in healthy but also in ischaemic limbs, caused by vasoactive effects of endothelial cell derivatives. In 1984, Furchgott & Zawadski discovered the endothelium-derived relaxing factor (EDRF), which corresponds to nitric oxide. When there is a sudden increase in blood pressure, EDRF is produced within the endothelium and diffuses quickly from the venules to the arterioles, leading to arterial vasodilation. With this mechanism, EDRF is considered an important control factor for systemic vascular resistance.

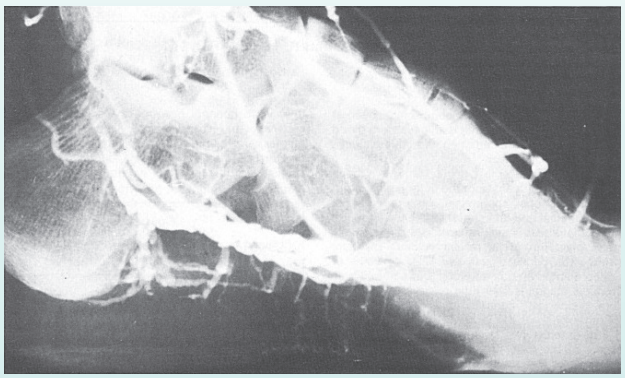
Prevention of leg venous thrombosis

Venous thrombosis is often accompanied by skeletal injury. Typically, anticoagulant drugs are used for prevention. However, there is a risk of bleeding which limits the use of pharmacological prophylaxis. In contrast, physical prophylaxis as artificial activation of the venous foot pump might also be effective in the prophylaxis of venous thrombosis. The physical prophylaxis is based on: "(a) the turbulence (…) which is induced in valve pockets, where thrombosis commonly begins; (b) release of EDRF, which not only produces hyperaemia but also inhibits and even reverses platelet aggregation; (c) release of prostacyclin; and (d) enhancement of fibrinolysis after tissue compression." (Gardner & Fox (1992), p. 1176).

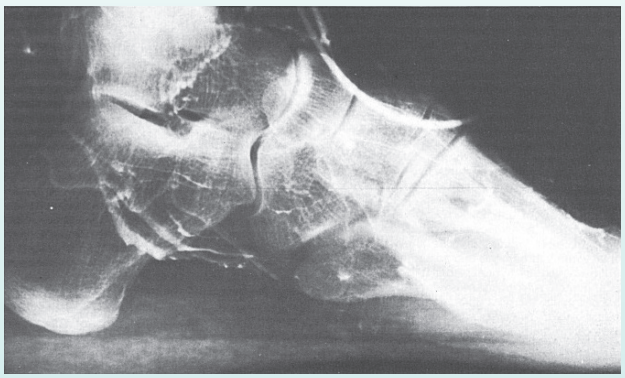
Artificial activation of venous foot pump by intermittent impulse compression

In contrast to typical compression devices, the A-V Impulse System™ – using intermittent impulse compression (IIC) technology[1] – inflates a cuff attached to the foot palm rapidly within 0.4 seconds, repeated in 20 seconds cycles. This compression impulse simulates natural gait and activates the venous foot pump. The clinical benefits of IIC-induced hyperaemia and EDRF are manifold, among others increased blood flow, reduction of swelling and pain relief.

A: Phlebogram of the foot without weight bearing[2]



B: Phlebogram of the foot with weight bearing[2]



[1] The technology of VADOplex® or A-V Impulse system™ foot pump can be described as "intermittent impulse compression (IIC)", a further development of the intermittent pneumatic compression (IPC). The pressure from the compression pad on the sole of the foot is developed in less than 0.4 seconds, whereby the blood from the venous plexus is accelerated like an impulse (see Gardner, A. M., & Fox, R. H. (1992). The venous footpump: influence on tissue perfusion and prevention of venous thrombosis. Annals of the Rheumatic Diseases, 51(10), 1173–1178. https://doi.org/10.1136/ard.51.10.1173)

[2] Gardner, A. M., & Fox, R. H. (1983). The venous pump of the human foot--preliminary report. Bristol Medico-Chirurgical Journal, 98(367), 109–112. Use of images covered by Creative Commons Attributions 4.0 International License.

Transitory hypoxic stimuli, venous vasodilation and enhanced perfusion of skin capillaries after intermittent compression treatment

Thorn, C. E., Adio, A. O., Fox, R. H., Gardner, A. M., Winlove, C. P., & Shore, A. C. (2021).
Intermittent compression induces transitory hypoxic stimuli, upstream vasodilation and enhanced perfusion of skin capillaries, independent of age and diabetes. Journal of Applied Physiology (Bethesda, MD, 1985), 130(4), 1072–1084. https://doi.org/10.1152/japplphysiol.00657.2020

Device: **VADOplex®**

Background

Although there is a good understanding of the role of shear stress in regulating blood flow in arteries, its effect on the microcirculation is less known. Therefore, the aim of the study was to investigate the effects of endothelial shear stress induced by intermittent impulse compression (IIC)[1] on microcirculation. It was further investigated if the effect on microcirculation is also affected by age and type 2 diabetes.

Design

Young participants (18-39 years), older participants (40-80 years) and older participants with type 2 diabetes (40-80 years) were included. A pneumatic compression impulse (1 second, 130 mmHg) was applied to the palm every 20 seconds by a hand pad using VADOplex® (OPED GmbH, Germany). Tissue oxygenation and blood flow were continuously recorded by reflectance spectroscopy and laser doppler fluximetry at the intermediate phalanges of the third finger. Capillary density was assessed by capillary video microscopy at the intermediate phalanges of the second finger after an acclimatization period (including the determination of maximum capillary density), before and after the 30 min VADOplex® intervention.

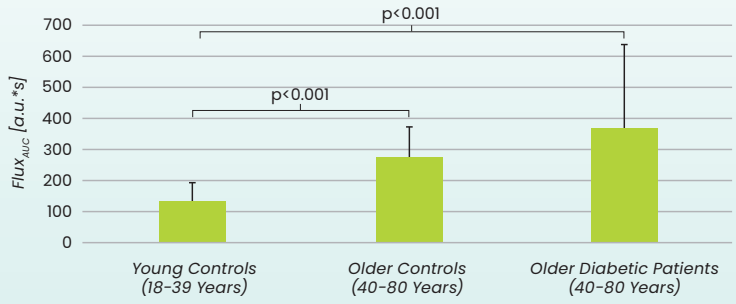
Results

A single compression impulse increases blood flow for ~2 seconds leading to a transitory reduction in blood oxygenation for 4 seconds. Afterwards, the blood flow rises again, reaching a second peak at 11 seconds after impulse. Hereby, the blood oxygenation increases again compared to the initial value, indicated by an increase in oxygenated haemoglobin and a decrease in deoxygenated haemoglobin. Further, this increase in blood oxygenation is induced by a delayed increase in blood flow resulting from a delayed vasodilation of upstream feeding vessels. This response was more pronounced in older participants and type 2 diabetes patients compared to young control subjects (p<.001). Additionally, IIC increased capillary recruitment in all subject groups.

Conclusion

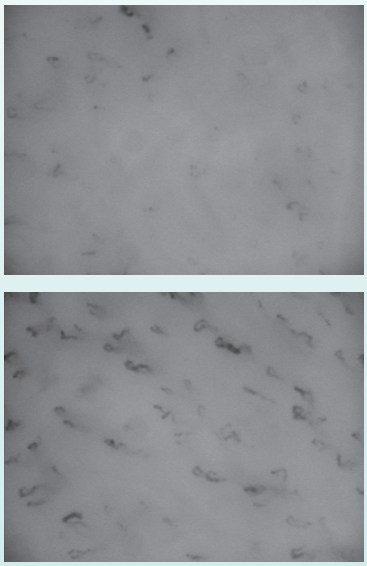
Overall, IIC can enhance capillary recruitment and microcirculation by temporary hypoxic stimuli and shear vasodilation of arterioles. These effects may be beneficial in the treatment of microvascular dysfunction and its consequences like impaired wound healing or ulcerations caused by cardiovascular and metabolic disorders. Finally, the results demonstrate that these effects are independent of age or diabetic status.

Effect of 30 min of Intermittent Pneumatic Compression to the Palm of the Hand on Dorsal Finger Skin Flux



AUC: Area under the Curve

Capillary Number in Dorsal Finger (Microscan)



Pre IIC
149* ‡ 9 no.mm-2

Post IIC
167* ‡ 6 no.mm-2

Images reprinted with the kind permission of C. E. Thorn. Images are snapshots taken from two 20-second videos.

[1] The technology of VADOplex® or A-V Impulse system™ foot pump can be described as "intermittent impulse compression (IIC)", a further development of the intermittent pneumatic compression (IPC). The pressure from the compression pad on the sole of the foot is developed in less than 0.4 seconds, whereby the blood from the venous plexus is accelerated like an impulse (see Gardner, A. M., & Fox, R. H. (1992). The venous footpump: influence on tissue perfusion and prevention of venous thrombosis. Annals of the Rheumatic Diseases, 51(10), 1173–1178. https://doi.org/10.1136/ard.51.10.1173)

Intermittent impulse compression enhances foot microcirculation in patients with arterial diseases

Abu-Own, A., Cheatle, T., Scurr, J. H., & Coleridge Smith, P. D. (1993).
Effects of intermittent pneumatic compression of the foot on the microcirculatory function in arterial disease. European Journal of Vascular Surgery, 7(5), 488–492. https://pubmed.ncbi.nlm.nih.gov/8405490/

Device: **A-V Impulse System™**

Background

In previous clinical trials, different non-operative treatments (e.g., drug treatment) for severe peripheral arterial occlusive disease (PAOD) produced poor results regarding microcirculatory blood flow or were accompanied by several side effects. Intermittent pneumatic compression, however, was shown to produce EDRF (endothelium-derived relaxing factor) and thus improve venous return, arterial vasodilation and artery blood flow. The aim of this study was to evaluate the effect of intermittent pneumatic compression of the foot's venous plexus on the microcirculation in PAOD patients. Blood flow and oxygenation were measured using Laser Doppler Fluxmetry and transcutaneous oxygen tension ($tcPO_2$).

Design

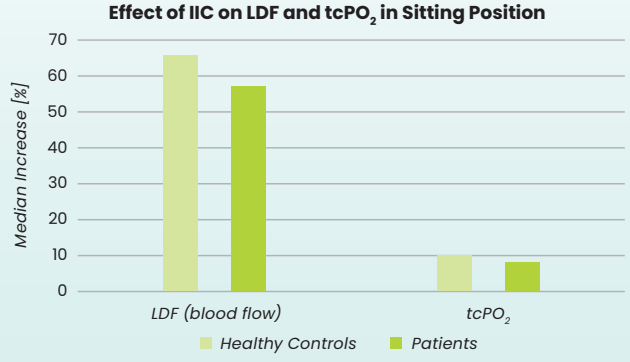
15 patients with PAOD (diabetic patients excluded) and 15 healthy subjects received intermittent impulse compression (IIC)[1] administered to the foot by using the A-V Impulse System™. Laser Doppler Flux (LDF) and $tcPO_2$ were measured on the big toe before, during and after a 10-minute period with the A-V Impulse on the big toe. The measurement was performed first while lying down and repeated while sitting up.

Results

In the supine position, resting LDF was significantly lower in patients with PAOD compared to healthy individuals, whereas resting $tcPO_2$ was not significantly lower in patients than in healthy individuals. While $tcPO_2$ increased significantly during sitting in the patient group (median increase 6 mmHg, 95% CI [3,10], $p<0.01$), LDF decreased significantly during sitting compared to lying (patients: median decrease 100 AU, 95% CI [70,125], $p<0.001$; healthy subjects: median decrease 205 AU, 95% CI [150,268], $p<0.001$). IIC induced only slight, non-significant, increases in $tcPO_2$ and LDF in both groups in supine positions. In contrast, IIC significantly increased LDF and $tcPO_2$ in patients (LDF: median increase 82 AU, 95% CI [60,130], $p<0.001$; $tcPO_2$: median increase 8 % respective 6 mmHg, 95% CI [4,10], $p<0.01$) and healthy subjects (LDF: median increase 124 AU, 95% CI [73,175], $p<0.001$; $tcPO_2$: median increase 10% respective 6,5 mmHg, 95% CI [4,9], $p<0.01$) while sitting.

Conclusion

According to the study, a reduction in LDF and $tcPO_2$ is typical in patients with PAOD when compared to healthy subjects. Further, a significant effect on microcirculatory blood flow of IIC in the sitting position could be shown. Enhanced microcirculatory blood flow might be mediated by the vasodilatory function of EDRF. Additionally, an increased arteriovenous pressure gradient, induced by the compression of the venous plexus and high hydrostatic pressure during sitting, might be a trigger for enhanced microcirculatory blood flow.



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Studies showing effectiveness of IIC in wound management

Short communication: intermittent impuls compression affects the wound micorenvironment positiverly

Eberlein, T., Schmitz, M. (2020).
Micro-Environmental Changes in Wounds are Significantly Influenced by Intermittent Pneumatic Impulse Compression (IIC). *Biomedical Journal of Scientific & Technical Research, 26(1).*
https://doi.org/10.26717/BJSTR.2020.26.004282

Device: **VADOplex®**

Background

Wound pH is an important factor when it comes to wound healing processes. It has been shown that reparative processes are started at acidic pH levels of around 6.5. In chronic wounds, however, there are higher pH values, which seems to be related to the character of wound exudate. There is limited evidence for the link between microcirculation and wound pH. Therefore, the authors investigated if an increased microcirculation, induced by intermittent impulse compression (IIC)[1], can decrease pH values and the temperatures in venous leg ulcers (VLU), thus accelerating wound healing.

Design

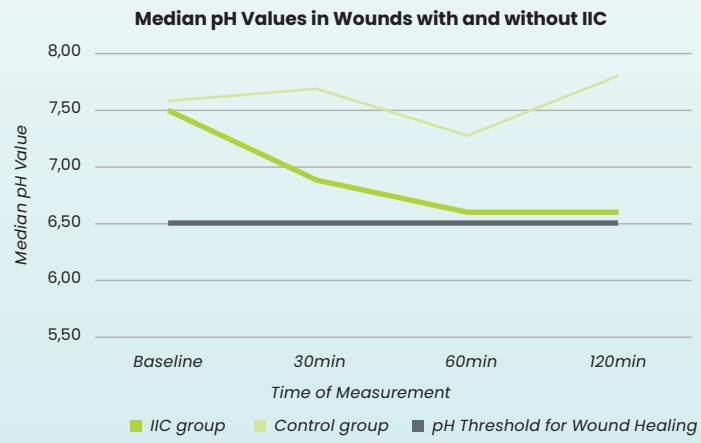
A total of 16 patients with venous leg ulcers (VLU) were included, 11 were assigned to receive IIC therapy (VADOplex®, OPED GmbH, Germany) for 2 hours via foot pad (f=3 pulses/min; pressure application time [single impulse] t_{Appl}= 1sec). Five patients were assigend to the control group and did not recieve IIC therapy. The affected legs of all patients were immobilised and elevated during those two hours. Measurements of the pH values were taken with a wound pH meter (TR 26, NAWA Technology, Nuremberg, Germany) at 4 different times: baseline, after 30 minutes, after 60 minutes and after 120 minutes.

Results

59 pH and temperature measurements were carried out in 11 patients with VLU. Over the testing period of 120 minutes, pH values in the IIC group decreased from 7.55 (7.2–8.2) at baseline to 6.75 (6.3–7.2) (t-test p=0.000). Wound temperature increased slightly in the same period as well, from 29.73°C (28.0–31.6) at baseline to 30.07°C (27.7°C–31.0°C) (t-test p=0.212). In the control group, mean pH values increased slightly from 7.62 (7.4–7.8) at baseline to 7.63 (7.4–8.0) after 120 minutes (t-test p=0,789). The wound temperature increased from 30.72°C (28.3–33.1) at baseline to 31.30°C (29.9°C–33.0°C) after 120 minutes (t-test p=0.389).

Conclusion

Wound pH in the IIC group decreased and thus improved significantly (p=0.000), the control group showed instead a slight increase of pH values. Lower wound pH values are considered to be beneficial to wound healing and there is evidence that healing processes are triggered at 6.5 and below. Wounds in the IIC group reached – within only 120 minutes – almost the desired pH value of 6.5, initiating reparative processes. In contrast, there was a significantly higher wound pH in the control group, which is not beneficial to wound healing. The results underline the suggestion that IIC may lower pH levels, support reparative processes and lead to faster wound healing of VLU.



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Prospective controlled study: intermittend pneumatic foot compression can improve walking ability in patients with symptomatic peripheral vascular disease

Delis, K. T., Nicolaides, A. N., Wolfe, J. H. N., Stansby, G. (2000)
Improving walking ability and ankle brachial pressure indices in symptomatic peripheral vascular disease with intermittent pneumatic foot compression: A prospective controlled study with one-year follow-up
Journal of Vascular Surgery, April 2000 (31), S. 650-661. https://doi.org/10.1067/mva.2000.103969

Device: **A-V Impulse System™**

Backround

Accompanied with peripheral arterial disease (PAOD), intermittent claudication significantly affects patients' quality of life. Mechanical methods have ermerged as an approach to enhance blood flow volume in the lower extremities of individuals suffering from PAOD. The aim of this study was to investigate whether these patients can benefit from a treatment with an intermittent impulse compression (IIC)[1] foot device (A-V Impulse System™), specifically in terms of gait distance and arterial haemodynamics.

Design

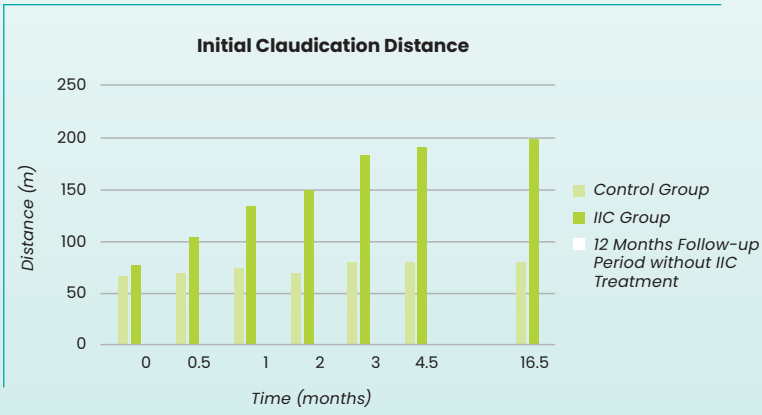
The study population consisted of 37 patients suffering from intermittent claudication. 25 patients were assigned to the IIC-Group and 12 patients to the control group. At baseline, the groups were equal regarding age, sex, risk factors, claudication distances, and ankle pressures. In the treatment phase (4.5 months), patients of the IIC group were treated with IIC for >4 h/day, patients in the control group did not receive any IIC treatment. All patients were encouraged to exercise on their own for ≥ 1 hour/day and were given aspirin (75mg/day). The following parameters were measured in each patient at day 0, at 2 weeks, and at 1, 2, 3 and and 4.5 months (treatment period): initial claudication distance (ICD), absolute claudication distance (ACD), resting ankle brachial index (r-ABI), ankle brachial pressure index after exercise (p-eABI), and popliteal artery volume flow. There was a reexamination of all patients after 12 months to assess the long-term effects of the treatment.

Results

After 4.5 months, initial claudication distance (ICD) increased in the IIC group by 146% ($p<0.001$), ICD did not improve significantly in the control group. While median absolute claudication distance (ACD) improved in the IIC group by 106% ($p<0.001$), there were no significant changes in the control group. In the IIC group, resting ankle brachial index (r-ABI) increased by 18% ($p<0.001$), in the control group no progress could be seen. Moreover, ankle brachial pressure index after exercise (p-eABI) grew in the IIC group by 18% ($p<0.001$), in the control group no improvements could be detected. Popliteal artery volume flow improved in the IIC group by 36%, which was, however, not significantly better than in the control group. In summary, at 4.5 months, ICD, ACD, r-ABI and p-eABI values were significantly better ($p<0.01$) in the IIC group compared to the control group. After 12 months, the values (ICD, ACD, r-ABI and p-eABI) in the AVI group were not statistically different, compared to the measurements at 4.5 months, instead, they continued to be significantly better than in the control group.

Conclusions

This study showed that the use of IIC in the A-V Impulse System™ was able to improve claudication distance in patients with stable intermittent claudication by more than 100%. The effect persisted until 12 months after treatment. Improved r-ABI and p-eABI values suggest an improved collateral circulation in claudication patients receiving IIC.



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Global vascular guidlines on the management of chronic limb-threatening ischemia

VADOplex® by OPED
VASCULAR IMPULSE TECHNOLOGY

Michael S. Conte, MD (Co-Editor), Andrew W. Bradbury, MD (Co-Editor), Philippe Kolh, MD (Co-Editor), John V. White, MD (Steering Committee), Florian Dick, MD (Steering Committee), Robert Fitridge, MBBS (Steering Committee), Joseph L. Mills, MD (Steering Committee), Jean-Baptiste Ricco, MD (Steering Committee), Kalkunte R. Suresh, MD (Steering Committee), M. Hassan Murad, MD, MPH, and the GVG Writing Group (2019).

Global vascular guidelines on the management of chronic limb-threatening ischemia.
Journal of Vascular Surgery, 69(6), 3S25S.e40. https://doi.org/10.1016/j.jvs.2019.02.016

Device: **Various**

Background

The Global Vascular Guidelines (GVG) represent a comprehensive clinical practice guideline for the diagnosis and treatment of Critical Limb-Threatening Ischemia (CLTI). It is considered the "Gold Standard" in the treatment of CLTI. In Chapter 7, Nonrevascularization Treatments of the Limb, the guidelines devote a section to Intermittent Pneumatic Compression (IPC)[1]. According to the authors, revascularization is the optimal treatment for CLTI. However, it is widely understood that many patients are not eligible for the procedure, mostly for anatomic or physiologic reasons. Neither is amputation an option for many patients. Therefore, the authors of GVG conclude, that there is still a large number of patients who might benefit from nonrevascularization-based treatments like IPC. The mechanism of action of IPC devices is as follows: IPC application increases the arteriovenous pressure gradient and activates the endothelial vasodilators. As a result, the venoarteriolar reflex is suspended, which in turn stimulates collateral artery growth. This mechanism leads to an increase of arterial flow, peak systolic velocity, end-diastolic velocity, and pulse volume. Regarding the effectivity of IPC there are several case studies and two controlled trials, but according to the authors of GVG, it is difficult to develop a systematic review and meta-analysis on IPC due to the heterogeneity of the available studies. However, the guidelines make a recommendation to consider IPC therapy in carefully selected patients who are not eligible for revascularization (moderate level of evidence).

Systematic review

The key reference for the recommendation is the systematic review by Abu Dabrh[2] from 2015, focusing on different nonvascularization-based treatments of CLTI. In this review a total of 19 studies with overall 2,779 patients were included.

Results and conclusions

IPC, like all nonvascularization-based treatments, did not show a significant effect on mortality. The risk of amputation was lower in patients receiving IPC (OR, 0.14; 95% CI [0.04, 0.55]), but a priori established subgroup analyses (combined vs single therapy; randomized vs non-randomized) showed no statistically significant difference. Results derived from single small non-randomized studies showed that IPC use was associated with statistically significant improvements in ulcer healing and amputation. However, the results need to be replicated and verified in larger randomized controlled trials.

[1] The technology of VADOplex® or A-V Impulse system™ foot pump can be described as "intermittent impulse compression (IIC)", a further development of the intermittent pneumatic compression (IPC). The pressure from the compression pad on the sole of the foot is developed in less than 0.4 seconds, whereby the blood from the venous plexus is accelerated like an impulse (see Gardner, A. M., & Fox, R. H. (1992). The venous footpump: influence on tissue perfusion and prevention of venous thrombosis. Annals of the Rheumatic Diseases, 51(10), 1173–1178. https://doi.org/10.1136/ard.51.10.1173)

[2] Dabrh, A. M. A., Steffen, M. W., Asi, N., Undavalli, C., Wang, Z., Elamin, M. B., Conte, M. S. & Murad, M. H. (2015). Nonrevascularization-based treatments in patients with severe or critical limb ischemia. Journal of Vascular Surgery, 62(5), 1330-1339.e13. https://doi.org/10.1016/j.jvs.2015.07.069

Abbreviations

ACD	Absolute Claudication Distance
AUC	Area under the Curve
CI	Confidence Intervall
CLTI	Chronic Limp-Threatening Ischemia
EDRF	Endothelium-Derived Relaxing Factor
GVG	Global Vascular Guidelines
ICD	Initial Claudication Distance
IIC	Intermittent Impulse Compression
IPC	Intermittent Pneumatic Compression
LDF	Laser Doppler Flux
OR	Odds Ratio
PAOD	Peripheral Arterial Occlusive Disease
p-eABI	Post-Exercise Ankle Brachial Index
rABI	Resting Anke Brachial Index
$tcPO_2$	Transcutaneous Oxygen Tension
VLU	Venous Leg Ulcer

This document refers to international Guidelines and recommendations. Please follow also the Guidelines valid in your country.

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