Contraindications - the VADOplex is contraindicated for patients where an increase of fluid to the heart may be detrimental, including some patients with congestive heart failure and those with pre-existing deep vein thrombosis, thrombophlebitis or pulmonary embolism. The device should be used with caution on the infected or insensitive extremity.

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Summary Clinical Review II Abstracts reference A-V Impulse System™

Peripheral Vascular Disease

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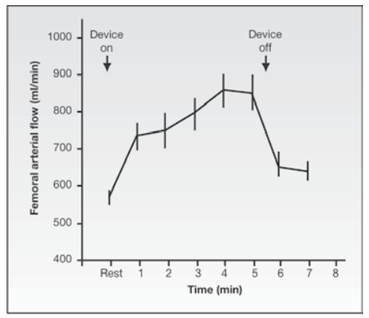
Contents

THE VENOUS FOOTPUMP: INFLUENCE ON TISSUE PERFUSION AND PREVENTION OF VENOUS THROMBOSIS

A.M.N. Gardner and R.H. Fox
TORBAY HOSPITAL, TORBAY, DEVON, UK
Annals of the Rheumatic Diseases, 1992, October, 51(10) pp1173-1178

Increased arterial blood flow following foot compression has been observed for over a century. Until recently there has been no satisfactory explanation for these observations. The discovery of endothelial cell derivatives, and most importantly endothelial derived relaxing factor (EDRF) has increased our understanding of the control of the microcirculation.
EDRF mediates the relaxation of arterial smooth muscle, and its production in the endothelium is stimulated by 'shear stress' caused by sudden pressure change. The short half-life of EDRF (6-50 seconds) corresponds well with the short duration of post-impulse compression hyperaemia observed with the use of the A-V Impulse System.

This graph illustrates the effect of impulse pumping on common femoral arterial flow in a patient with a femoropopliteal arterial block.



ARTERIAL FLOW ENHANCEMENT BY IMPULSE COMPRESSION

R.H. Morgan, G. Carolan, J.V. Psaila, A.M.N. Gardner, R.H. Fox and J.P. Woodcock
CARDIFF, WALES, TORQUAY AND DEVON, ENGLAND
Journal of Vascular Surgery 1991, January/February, pp8-16

This study was prompted after preliminary observations of rapid relief of ischaemic rest pain following application of a foot compression device (A-V Impulse System™, Orthofix Vascular Novamedix, Andover, UK). The aim of this study was to quantify the immediate effects of impulse compression on popliteal artery blood flow.

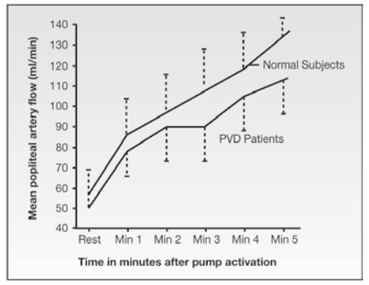
12 normal subjects (Doppler ankle/brachial pressure index >1.0) and 10 patients with peripheral vascular disease (mean Doppler ankle/brachial pressure index 0.62, range 0.33 – 0.74) were studied.
None of the patients were diabetic and none were currently under treatment with peripherally active medication.

Popliteal artery volume flow was calculated by means of a duplex ultrasound imager interfaced with a Doppler spectrum analyzer.

Over the 5 minute period of pump application, mean popliteal blood flow increased by 93% ($p<0.0001$) in normal subjects and 84% ($p<0.003$) in peripheral vascular disease patients. In 5 normal control subjects, a 'placebo' device produced no significant change in flow ($p>0.1$).

The A-V Impulse System temporarily increases subsequent flow in the popliteal artery both in normal subjects and in patients with arterial obstruction. It is suggested that the hyperaemic effect may be explained by the liberation of endothelial derived relaxing factor (EDRF), a powerful relaxant of vascular smooth muscle, produced in response to sudden pressure changes (haemodynamic shear-stress) within the venous system.

Impulse pumping whatever its physiologic explanation, has a number of potential applications in the clinical field. In ischaemic limbs it can increase blood flow and relieve rest pain and so is likely to limit tissue damage in patients awaiting surgery or when surgery has nothing to offer. After arterial grafts, impulse pumping may have a place in maintaining uncertain graft flow.



EFFECT OF FOOT COMPRESSION ON THE VELOCITY AND VOLUME OF BLOOD FLOW IN THE DEEP VEINS

B. Andrews, K. Somerville, S. Austin, N. Wilson and N.L. Browse
DEPARTMENT OF SURGERY, ST THOMAS' HOSPITAL, LONDON
British Journal of Surgery, 1993, February, Vol 80, 198-200

10 healthy patients in a supine, 10 degree foot down position were studied. Using a duplex scanner the effects of altering pressure, pulse duration and frequency of foot compression on the velocity and volume of blood flow in the superficial femoral and popliteal veins were quantified. In 20 legs, foot compression of 50, 125 and 200mmHg significantly increased the maximum venous blood flow by 9.0, 13.4 and 15.1 ml/s respectively ($p<0.001$). Conversely, reducing the frequency of compression from 6 to 3 cycles per min significantly increased the rise in peak flow from 10.1 to 14.8 ml/s ($p<0.001$). Changing the duration of compression from 1 to 3 seconds had no significant effect on peak flow. Increased blood flow is best achieved with high-pressure, low-frequency foot compression. Increasing the duration of compression beyond 1 second has no effect on augmentation of flow in the deep veins. A typical venous flow response, as measured in the femoral vein, with the application of the A-V Impulse System clearly showed a surge of blood flow through the entire leg.

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

K.T. Delis, A.N. Nicolaides, J.H.N. Wolfe and G. Stansby
ST MARY'S HOSPITAL, LONDON, UK
Journal of Vascular Surgery, 2000, April, (31) 4, pp650-661

The purpose of this study was to determine the effect of the A-V Impulse System on claudication distance and arterial haemodynamics in patients with intermittent claudication caused by peripheral vascular disease.
37 patients with stable intermittent claudication were recruited; 25 received the A-V Impulse System, for >4 hours/day for 4.5 months (Group 1). The remaining 12 patients acted as controls (Group 2).

Both groups were advised to exercise unsupervised for > 1 hour daily and received aspirin 75mg/d. 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 were measured at day 0, 2 weeks, and 1, 2, 3 and 4.5 months. On completion of the treatment period both groups continued with aspirin and unsupervised exercise and were re-examined after 12 months.
Over the 4.5 months of active treatment Group 1 results showed that, median ICD increased by 146% ($p<0.001$); median ACD improved by 106% ($p<0.001$); median r-ABI improved by 18% ($p<0.001$); median p-eABI in group 1 improved by 110% ($p<0.001$) and mean popliteal artery volume flow increased by 36% ($p<0.001$). No significant changes were found in Group 2 when measuring these parameters. Twelve months post-treatment, walking ability and ABIs in Group 1 were not statistically different from those at 4.5 months and remained significantly better than those of the control subjects.
The A-V Impulse System used at home for 4.5 months increased claudication distance by over 100%. Associated increases in r-ABI, p-eABI and arterial calf inflow suggest an improved collateral circulation. Maximum benefits seem to be offered over the first three months. Treatment benefits are maintained 1 year after treatment.

Demographics, walking ability, hemodynamics, and risk factors in the study groups.

	Group 1 (n=25)[1]		Group 2 (n=12)[2]		Significance (group 1 vs 2)
Male/female	17/8	7/5			NS[3]
Age (y; range)	68	(58-81)	65	(60-78)	NS[4]
ICD (m; interquartile range)	78	(65-102)	69	(50-92)	NS[4]
ACD (m; interquartile range)	124	(100-160)	134	(89-202)	NS[4]
r-ABI (interquartile range)	0.57	(0.48-0.62)	0.56	(0.52-0.6)	NS[4]
p-eABI (interquartile range)	0.21	(0.07-0.26)	0.24	(0.17-0.3)	NS[4]
Popliteal artery volume flow (mL/min; interquartile range)	100	(59-163)	110	(70-155)	NS[4]
Smoking (n)	1/25		1/12		NS[3]
Diabetes mellitus (n)	3/25		1/12		NS[3]

[1] IPC $_{foot}$ + asprin [2] Asprin [3] Chi-square test ($P > .05$) [4] Mann-Whitney test ($P > .05$)

THE PLANTAR VENOUS PLEXUS AND APPLICATIONS OF A-V IMPULSE SYSTEM

J.V. White and J.I. Zarge
TEMPLE UNIVERSITY, PHILADELPHIA, USA
Review Article

THE A-V IMPULSE SYSTEM AND POST-REVASCULARISATION OEDEMA

Patients undergoing distal vascular reconstruction for limb salvage were treated with the A-V Impulse System. Use of the footpump on the operative leg began in the recovery room and continued for 7 days. Calf and ankle circumference were measured daily. The preoperative measurements were taken as baseline. Wound complications were also recorded.
Preliminary results in 10 patients demonstrated a significant benefit of using the A-V Impulse System after lower extremity revascularisation.
Oedema was markedly reduced and there were no wound complications in the immediate postoperative period in patients treated with the A-V Impulse System.
However, the control group demonstrated a progressive increase in calf circumference and wound complications occurred in 3 of 5 patients in the control group.

TREATMENT OF UNRECONSTRUCTABLE END STAGE DISTAL ISCHAEMIA

To determine whether augmentation of venous outflow can result in enhanced arterial inflow in patients with severe peripheral arterial occlusive disease, 7 extremities in 5 patients have been treated.
Four patients presented with toe ulcers, rest pain and had unreconstructable vascular disease by angiography. One patient had severe distal disease and rest pain but had to delay surgery until cardiac problems could be controlled. Ankle brachial indices ranged from 0.0 – 0.31.
The A-V Impulse System was used for 4-6 hours each day. All patients had at least a 1cm reduction in calf circumference and reported a significant reduction in rest pain within 2 days of treatment. One patient demonstrated a return of her dorsalis pedis pulse. Toe ulcers began to heal. These preliminary data strongly suggest that the AV Impulse System may be of benefit in those patients with severe distal ischaemia and unreconstructable vascular disease.

EFFECTS OF INTERMITTENT PNEUMATIC COMPRESSION OF THE FOOT ON THE MICROCIRCULATORY FUNCTION IN ARTERIAL DISEASE

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DEPARTMENT OF SURGERY, UNIVERSITY COLLEGE AND MIDDLESEX SCHOOL OF MEDCINE, LONDON, UK
European Journal of Vascular Surgery, 1993, September, Vol 7 pp 488-492

The management options available for patients with severe peripheral occlusive arterial disease (POAD) who are not suitable for reconstructive surgery or angioplasty are very limited. Drug treatment to improve the microcirculatory blood flow in such patients has been advocated but most clinical trials have produced disappointing results.

The aim of this study was to evaluate the effect of mechanical activation of the foot pump on the microcirculation of the skin in patients with peripheral occlusive arterial disease.

15 patients with POAD (mean Doppler ankle brachial pressure index 0.52, range 0.31-0.68) and 15 control subjects had the A-V Impulse System applied to the foot. Diabetic patients were excluded from the study. Laser Doppler flux (LDF) and transcutaneous oxygen tension (tcPO2) were measured on the big toe with the subject supine, before, during and after a 10 minute period of foot pumping. The study was repeated with the subject sitting.

On sitting there is a fall in LDF and a rise in tcPO2. Application of intermittent pneumatic compression to the foot in the sitting position resulted in an increase in LDF. In patients, the median percentage increase was 57% and the median difference was 82 arbitrary units (AU) (95% CI 60-130, $p<0.001$). In controls, the median percentage rise was 66% and the median difference was 124 AU (95% CI 73-275 $p<0.001$). There was a corresponding 'further' increase in tcPO2 in both groups of subjects. In patients, the median percentage increase was 8%, in controls the median percentage increase was 10% ($p <0.01$).

It can be concluded that intermittent pneumatic compression of the foot in the dependent position increases LDF and tcPO2. Mechanical activation of the venous foot pump may improve the microcirculatory blood flow suggesting the possibility of a new form of treatment for patients with rest pain and ischaemic ulcers.

IS IMPULSE COMPRESSION OF THE FOOT A POTENTIAL THERAPY FOR DIABETIC PATIENTS WITH REST PAIN AND TOE OR FOOT ULCERS OF A VASCULAR ORIGIN?

K. Van Acker, A. Bouten, P. Abrams, D. Ballaux, Prof P. Van Schil, F. Van den Brande.
DEPARTMENT OF ENDOCRINOLOGY/FOOT CLINIC/DEPARTMENT OF VASCULAR SURGERY, UZA, ANTWERP, BELGIUM
International Union of Angiology, 2000, May, Ghent Belgium

The objective of this pilot study was to investigate whether plantar impulse compression could be potentially efficacious in the treatment of rest pain, foot or toe ulcers where the underlying cause was vascular. Diabetic patients with toe or foot ulcers, with or without rest pain were included. All patients included had absence of dorsal pedal pulse and posterior tibial pulse together with ABPI < 0.8. Seven patients completed the study.

Patients received in-hospital training for 2-5 days to prepare them for a minimum of 6 hours of impulse compression per day at home. Follow up visits were at 14 days, one month, and then once a month. At each visit, ulcer size and rest pain were recorded.

Patient (age, sex) Diabetes (type, duration)			Rest Pain	Ulcers
1	82 years. Female Type I, 22 years	Before After	Yes Reduced	3 toe ulcers No change
2	60 years. Male* Type I, 31 years	Before After	None	2 ulcers (toe+ball) Both healed
3	73 years. Male Type II, 17 years	Before After	None	1 toe ulcer Ulcer healed
4	77 years. Male Type II, 16 years	Before After	Yes Reduced	1 heel ulcer (large) Ulcer healed
5	82 years. Male Type II, 23 years	Before After	None	4 toe ulcers No change.
6	89 years. Female* Type II, 30 years	Before After	Yes Reduced	1 toe ulcer Ulcer healed
7	72 years. Female Type II, 15 years	Before After	None	1 hallux valgus ulcer Reduced in size

These preliminary results show potential efficacy in the treatment of both rest pain and ulcers of vascular origin. In clinical usage of the foot pump since the submission of this data, the authors are beginning to observe a high rate of reduction of rest pain in patients using the A-V Impulse System.

EFFECT OF FOOT IMPULSE TECHNOLOGY IN PATIENTS WITH DIABETIC OR ISCHAEMIC ULCERS

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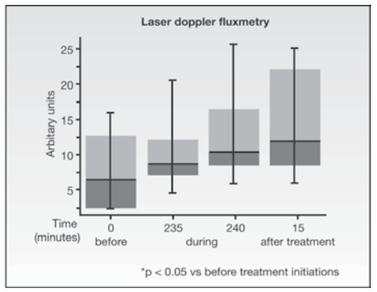
International Union of Angiology, 2000, May, Ghent Belgium

Therapeutic options for treatment of patients with severe limb ischaemia, who are not suitable for endovascular or surgical recanalisation, are limited. There is some evidence that impulse compression of the foot could be another alternative for conservative treatment of ischaemic or diabetic ulcers. This study investigated whether impulse compression of the foot has a similar effect on foot microcirculation as prostanoids. For this purpose single channel laser Doppler fluximetry was used.
10 patients (8 male, 2 female, 7 diabetic) with arterial ulcers at their forefeet were investigated. Treatment and measurements were performed with the patients in a supine position with the upper parts of their bodies slightly elevated (20-30 degrees). The A-V Impulse System was used for four hours. Laser Doppler flux was determined on the border of the ulcers by means of a laser blood flow monitor (MBF 3D; Moor Instruments, England). Measurements for 300 seconds were performed before, after 235 minutes, at termination of intermittent pneumatic compression and 15 minutes after the end of intermittent pneumatic compression.

Laser Doppler flux before intermittent pneumatic compression was (MEAN +/- SD) 7.6+/-4.9 AU. After 235 minutes of intermittent compression, flux increased to 9.6+/-4.9 AU ($p>0.05$). At termination of intermittent compression, flux was almost statistically different in comparison with flux before treatment 12.1 +/-7.5 AU ($p<0.06$). 15 minutes after the end of treatment flux was highest, 14.5 +/- 7.5 AU, and statistically significant compared with values before treatment ($p<0.05$).

The data indicates that the A-V Impulse System effects skin microcirculation in patients with severe limb ischaemia.



Even after the termination of intermittent pneumatic compression with the A-V Impulse System, the effect is prolonged and still increases. These findings could explain the promising clinical action of the A-V Impulse System for patients with severe peripheral arterial occlusive disease.

	N	Mean ± SD
Total	10	
Male	8	
Female	2	
Age (years)		69 ± 7.5
Height (cm)		175 ± 7
Weight (kg)		75 ± 14.1
Risk Factors		
Cigarette smoking	8	
Diabetes mellitus (OGTT, HbA1c)	7	
Hypercholestraemia (>200mg/dl)	4[1]	
Hypertension (>140/80mmHg)	4[1]	
Hyperuriceaemia (>7mg/dl)	2[1]	
Hypertriglyceridaemia (>170mg/dl)	1[1]	
Arterial pressures of the investigated legs		
Brachial artery (mm Hg)		144 ± 21
Anterior tibial artery (mm Hg)		109 ± 50[2]
Posterior tibial artery		104 ± 49[2]
Toe pressure (mm Hg)		41 ± 9[3]
Site of ulcers		
Toes	5	
Forefoot	1	
Ankle / heel	4	

[1] Pathologic values despite therapy
[2] Poor or missing compressibility of ankle arteries included
[3] In case of poor compressibility

AN ASSESSMENT OF THE EFFECT OF THE FOOT PUMP ON VENOUS EMPTYING IN CHRONIC VENOUS INSUFFICIENCY

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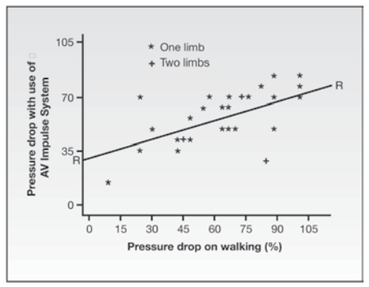
Phlebologie 1989, John Libbey Eurotext Ltd pp69-71

This investigation was undertaken to compare the efficiency of the foot pump with the calf pump in patients with venous insufficiency. 23 patients were studied, all had clinical signs of venous insufficiency.

The venous system of each limb was assessed by means of duplex scanning. By this means, limbs were categorised into groups; those with deep vein incompetence, those with superficial vein incompetence, and those with incompetent perforating veins.
Ambulatory and resting venous pressures where then recorded. The A-V Impulse System was then applied and resting venous pressure and drop in pressure was calculated.

The drop in pressure produced by the foot pump was found to closely parallel the pressure drop produced by walking. The results suggested that within the foot there is a powerful stimulus to venous emptying which is as significant as the calf muscle pump. The mechanism is effective in all types of venous insufficiency: deep, superficial and perforator incompetence.



Legend

(WM-STVX-XX) Original study number
FIT Foot Impulse Technology
DBS Circulatory disorders
pAVK Peripheral vascular disease
SD Standard deviation
LDF Laser Doppler flow velocity
$tcPO_2$ Transcutane oxygen tension
ICD Initial claudication distance
ACD Absolut caudication distance
p-e-ABI Post exercise ankle brachial pressure index
r-ABI Resting ankle brachial pressure index
ABPI Ankle-brachial-pressure-index