Effect of passive ankle movement in the sitting position on the symptoms of chronic venous insufficiency with long-term observation

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Abstract

Background. Chronic venous insufficiency (CVI) is the most common vascular disease. One major risk factor for its development is either long-term sitting or standing in the same position and the nature of the work performed.

Objectives. This study aims to assess the effectiveness of passive ankle movement in the sitting position performed using the Bella Vena robot for the symptoms of CVI with long-term observation.

Materials and methods. A group of 58 patients (mean age: 59.69 ±14.59 years) with CVI in CEAP (Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)) classification categories 2 and 3, and a group of 37 (mean age: 51.49 ±14.86 years) healthy volunteers performing sedentary work for at least 6 h during the working day were enrolled into the study. The total duration of observation lasted 8 months (8 visits), during which the following parameters were assessed at the beginning and end of this period: pain intensity (according to the visual analogue scale (VAS)), level of saturation on the toe, pulse rate, and lower limb Doppler ultrasound evaluation of reflux parameters.

Results. The exercises used in people with CVI resulted in a significant reduction ($p \leq 0.01$) in the occurrence of symptoms. Among all respondents, after 8 months of exercise, a significant reduction in pain level according to the VAS of the lower limbs, an improvement in saturation at the toe level, and a reduction in venous reflux was recorded ($p \leq 0.05$).

Conclusions. Home exercises with the use of an automatic exercise rehabilitation device alleviated significant symptoms in patients with CVI and improved the calf muscle pump.

Key words: chronic venous insufficiency, home exercises, calf muscle pump

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Background

Chronic venous insufficiency (CVI) is a common health problem which may cause significant morbidity and mortality. It develops when the venous pressure is increased and blood return is impaired. Several mechanisms may result in blood flow impairment, including incompetent valves (superficial or deep veins), perforating veins, venous obstruction, or a combination of these mechanisms. This leads to general or local venous hypertension, mainly while standing or ambulating, contributing to macro- or microcirculatory hemodynamic impairments and local tissue ischemia.[1,2] Prolonged standing or sitting are important risk factors of CVI; therefore, it is very important during initial and regular check-ups in people who do this kind of work to control the state of the venous system of the lower limbs. At the same time, employees in such workplaces should be informed about the health effects of prolonged sitting and standing and possible preventive measures.[3] Occupational leg symptoms, especially leg swelling, are associated with feelings of tiredness and heaviness of the legs and leg pain. Hence, reducing leg swelling is important in preventing the development of CVI.

The calf muscle pump is also important for venous competence – it is called the peripheral heart. Through contraction of the calf muscles, the veins are squeezed, and the blood is pumped upward with the help of one-way valves.[4] Numerous authors report satisfying results of the use of supervised training to activate the calf pump through planned dorsal and plantar flexion of the foot in patients treated for CVI.[5,6] In Polish health service, no procedures are used embracing physiotherapy in patients suffering from CVI; that is why we offer the Bella Vena platform for people who work in the sitting position.

Objectives

This study aimed to assess the effectiveness of passive ankle movement in the sitting position with the use of the Bella Vena robot for the symptoms of CVI over a long-term observation. The influence of passive ankle movement on blood flow from the lower extremities, measured by the duration of valvular reflux and the circumference of the shins, was also examined.

Materials and methods

The trial was conducted in accordance with the guidelines proposed by the institution supervising the trial, which approved the clinical trial protocol, and the institution intermediating the trial for the National Centre for Research and Development. The study had permission to start clinical trials from the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (approval No. U.D.WM.DNB.83.2018 issued on November 19, 2018). This study has been approved by the Bioethics Committee of the Medical University of Silesia in Katowice (approval No. MIDMED/BV/2017, resolution No. 48/2017), and each participant received and signed a consent form to participate in the study. The study was conducted in accordance with the Declaration of Helsinki of 1975, as revised in 2008.

In the beginning, the study included 102 participants. Seven people did not qualify for the study (3 men and 4 women), so 95 patients met the inclusion criteria for the study. They were divided into 2 groups: 1) CVI group – 58 patients (16 men and 42 women) with CVI and a CEAP (Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)) classification of 2 and 3; and 2) control group – 37 healthy volunteers (20 men and 17 women) performing work in a sitting position for at least 6 h during each working day.

The selection of the study group was deliberate. Members of the group were recruited via traditional post (an invitation letter). The median age of group participants was 51–63 years, the body mass 73–74 kg and the body mass index (BMI) 25.31–27.49 kg/m^2 (Table 1). This group of patients had symptoms of CVI and had not been previously treated with mechanical rehabilitation devices.

The exclusion criteria consisted of deep vein thrombosis of the lower extremities, thrombosis of the superficial vein system in the lower extremities, acute inflammation in the venous system of the lower extremities without thrombosis, inflammation of all joints of the lower limbs, pregnancy and breastfeeding, plaster casts preventing movement in the ankle, knee and hip joints, inability to adopt the appropriate body position to use the device (contractures in the joints, lack of mobility of the joints), cardiovascular diseases, commission of the attending physician not to use this type of device, other diseases that prevent the use of the device in accordance with the instructions for use, a severe general condition of the patient, or insufficient physical and mental abilities of the patient to independently operate the product (unless it was operated under the constant supervision of the caregiver).

Parameter measurements

The total duration of observation was 8 months (8 visits), and the following parameters were assessed at the beginning and end of this period: assessment of pain intensity – according to the VAS, level of saturation on the toes, pulse rate, lower limb Doppler ultrasound evaluation of reflux (right popliteal vein, left popliteal vein, right small saphenous vein outlet, left small saphenous vein outlet, right great saphenous vein outlet, left great saphenous vein outlet, right femoral vein, and left femoral vein), measurement of the right and left shin circumference using a measuring tape, and subjective patient assessment regarding

Table 1. Demographic and biometric data of the respondents

Variable	Both groups (n = 95)	CVI group (n = 58)	Control group (n = 37)
Age [years]			
Min	25	25	25
Q1	46	50	40
Me	58	63	51
Q3	69	70	62
Max	83	83	78
Body height [cm]			
Min	149	149	158
Q1	160	159	165
Me	166	164.5	171
Q3	173	170	177
Max	187	185	187
Body mass [kg]			
Min	50	56	50
Q1	66	67	66
Me	73	73	74
Q3	84	85	80
Max	125	125	107
BMI [kg/m^2]			
Min	18.98	19.61	18.98
Q1	23.89	24.65	22.84
Me	26.71	27.49	25.31
Q3	29.35	30.18	27.04
Max	41.44	41.44	36.17

Min – minimum; Max – maximum; Me – median; Q1 – 1st quartile; Q3 – 3rd quartile; BMI – body mass index; CVI – chronic venous insufficiency.

the degree of reflux (scale 0–4). Doppler ultrasound examination with color flow imaging was performed after 15 min of adaptation of the patient with the SonoScape S8 portable ultrasonograph (SonoScape Medical Corp, Shenzen, China) and linear probe (frequency 5–7.5 MHz). The examination was performed in a sitting position.

Reflux was assessed after the transducer was placed at the great saphenous vein (Vena saphena magna) mouth level after the cough test. The assessment of reflux in the popliteal vein was performed at the exit of the small saphenous vein by pressing the calf muscle. All ultrasound examinations were performed by 1 doctor who was authorized to conduct this type of examination and could correctly interpret the examination results.[7,8]

The case report form (CRF) contained data on the occurrence of edema of the legs, skin cyanosis, muscle cramps (involuntary contractions), leg heaviness, patients bedridden or using wheelchair (i.e., immobilized patients), residual movements in the shoulder girdle, and other symptoms. Subsequent visits, except for the 1st one, encompassed the same questions, physical examination and imaging test. The visits took place every 4–5 weeks.

Intervention

To improve the quality of life of patients in the study groups, the Bella Vena device forced movement in the ankle joint to activate the calf pump. The Bella Vena device is an automated platform for exercising the lower limbs by forcing the heel–toe–heel movement of the foot at a properly selected foot inclination angle and speed of movement. The user places both feet on the exercising platform and then activates the device using the infrared (IR) remote control. Thanks to the properly designed movement of the platform that simulates gait, the Bella Vena device gives the possibility of training in the form of foot movement, activating the calf muscles. The so-called calf pump improves the outflow of blood from the lower limbs. While the device is operating, movement is forced in the ankle joints by the appropriate tilting of the training platform on which the feet are placed. The direct current DC motor installed in the Bella Vena device works in accordance with the values programmed in the microcomputer's memory – number of repetitions, speed of movement and angle of the platform. The mechanical structure of the device is responsible for the platform's inclination angle. The pendulum movement of the platform is possible thanks to a specially designed drive transmission system from the engine to the movable part of the platform. The operation of the device was selected in such a way as not to exceed the motion limits for the ankle joint, including the limit of the ankle flexion angle, since excessive movement can damage the joint. The device is powered by the 230 V mains through the alternating current/direct current (AC/DC) adapter that reduces the voltage supplied the device to a value that is safe for humans – 24 V DC. The Bella Vena device allows to exercise 2 feet at the same time or only 1 – left or right, depending on the user's needs. The casing of the Bella Vena device is made entirely of aluminum, while inside there is a DC motor with electronics controlling the motor operation and a drive transmission system. The study subjects used the device once a day for 30 min, and the frequency of the platform swing was 1 swing per second. The swing angle was 23°. During the 8 months of physical therapy at home, patients also had the opportunity for a telephone consultation with the physical therapist supervising this form of treatment. The device, before it was transferred for testing with the participation of patients, was subjected to a safety test for selected points of the PN-EN 60601 standard for medical devices by the Institute of Medical Technology and Apparatus in Zabrze (Poland) and KOMAG in Gliwice (Poland), where tests were carried out to obtain the International Protection Rating (IP) degree. The physical parameters of the device were selected in such a way that the device would be suitable for 90% of the population. The device is intended for people with a maximum weight of 120 kg. The components of the device in the form of electronics, motor, power supply, and construction were selected for this purpose. For people over 120 kg, a modified version

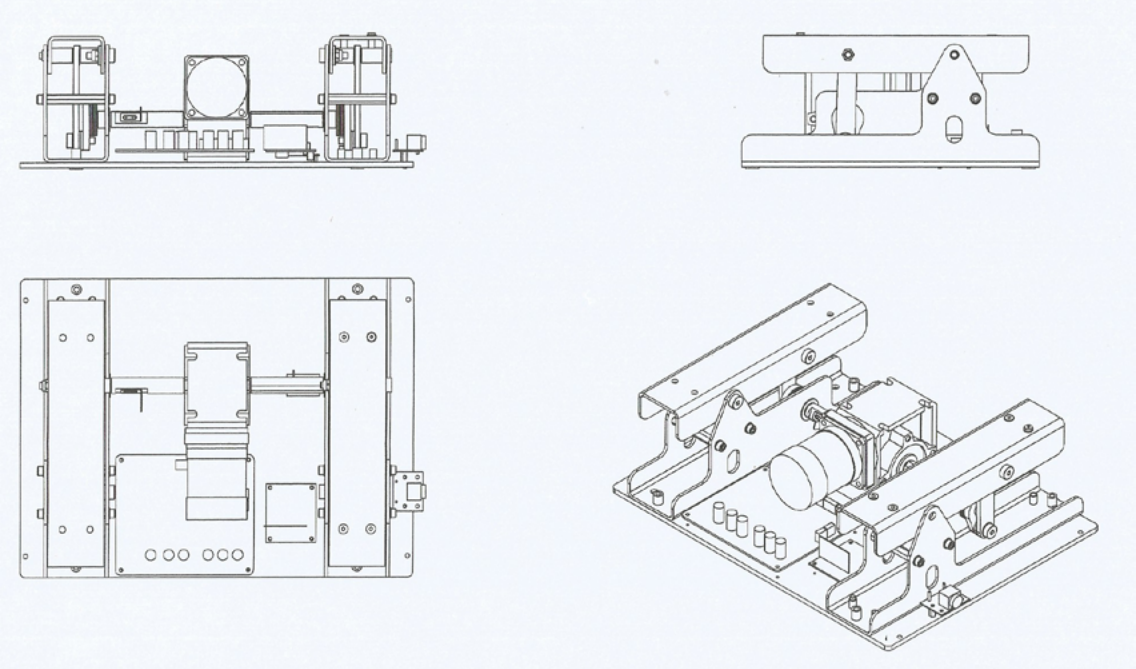

Fig. 1. Diagram of the Belle Vena device – internal view

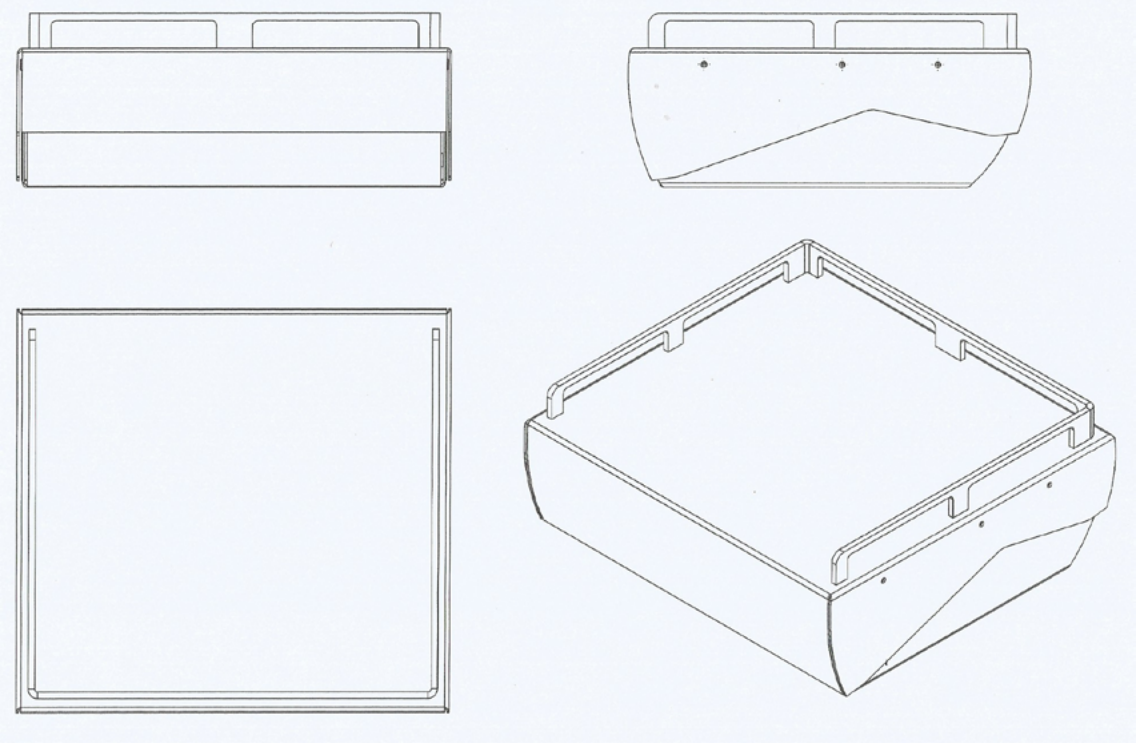

Fig. 2. Diagram of the Belle Vena device – external view

of the device was created, the so-called HD (heavy duty) version, where the appropriate design and electronics can cope with the increased weight of the lower limbs (Fig. 1,2).

Statistical analyses

To select an adequate statistical test to compare the studied groups, the Shapiro–Wilk normality test was used for all the tested variables; the distribution was not normal ($p < 0.05$). Following the above analysis, the nonparametric Wilcoxon test (continuous variables) and the McNemar test (nominal variables) were used. Moreover, the basic descriptive statistics were calculated: the percentage frequency of occurrence (nominal variables), median, and 1st and 3rd quartile (Q1, Q3). The results at a $p \leq 0.05$ were considered statistically significant.

Results

The difference in body weight of the studied groups was not statistically significant. In the group of people with CVI, the BMI was higher than in the control group (Table 1).

There was a statistically significant reduction of edema in 28.42% of the whole study population and of night cramps in 35.79%, while 29.47% of subjects reported a reduction in leg heaviness. Regarding cyanosis of the skin and problems with walking, no statistically significant differences were observed ($p > 0.05$; Table 2).

The exercises used in the group of people with CVI have resulted in a significant alleviation ($p \leq 0.001$) between the 1st and the last follow-up visit regarding edema of the legs, night muscle cramps, leg heaviness, and other problems. In the control group, in terms of other symptoms, a significant improvement was noted for 21.62% of the respondents (Table 2).

In all respondents, after 8 months of exercise, a significant reduction in pain level of the lower limbs according to the VAS, an improvement in saturation at the toe level, and a reduction in venous reflux was recorded. The reduction in venous reflux during the examination of the Doppler ultrasound in the control group was not statistically significant except for the right popliteal vein, right femoral vein and left femoral vein. The reduction in venous reflux during the examination of the Doppler ultrasound in the group with CVI was statistically significant for the right popliteal vein, left popliteal vein, right small saphenous vein outlet, right femoral vein, and left femoral vein ($p > 0.05$; Table 3). The differences in the measurement of the circumference of the right and left shin in the control group and CVI group were statistically insignificant ($p > 0.05$; Table 3).

The statistical analysis of the difference in reflux values during the subjective assessment of the patient with a scale of 0–4 was significant in the CVI group and both groups ($p > 0.05$; Table 3).

Discussion

The CVI is not a disease that directly threatens the patient's life, but it significantly reduces the everyday comfort of life. The chronic nature and severity of symptoms make normal functioning in society difficult, and in extreme cases impossible. The analysis of the obtained results indicated a significant alleviation of the symptoms of CVI in all 58 patients with CVI symptoms and healthy volunteers in long-term follow-up. The attenuation in subjective symptoms was associated with a reduction in venous reflux in the group with CVI. The alleviation of these symptoms confirms the positive effect of the calf pump on the venous system through the mechanical effect of the platform forcing movement in the ankle joint.

The veins of the lower extremity include the superficial and deep veins, which are defined by their respective relationships to the muscular fascia. The deep veins of the lower extremities primarily drain muscles and are encompassed by muscular fascia. Venous return from the lower extremities is vitally dependent on the action of the foot, calf and thigh muscle pumps, with approx. 90% of venous return attributed to these muscle structures during ambulation. Among these pumps, the calf muscle pump plays the pivotal role, reflected in the fact that it has the largest capacitance and generates the highest pressure, with an ejection fraction (EF) of approx. 65% in healthy subjects.[9,10] Calf muscle pump failure is a therapeutic target

Table 2. Values of study variables – symptoms

V1. Occurrence of symptoms		V8. Both groups (n = 95)		V8. CVI group (n = 58)		V8. Control group (n = 37)		V8. Both groups (n = 95)		V8. CVI group (n = 58)		V8. Control group (n = 37)	
		yes	no	yes	no	yes	no	McNemar test (df = 1)	p-value	McNemar test (df = 1)	p-value	McNemar test (df = 1)	p-value
		%	%	%	%	%	%						
Edema of the legs	yes	15.79	28.42	24.14	37.93	2.70	13.51	17.633	<0.001	20.045	<0.001	0.125	0.728
	no	3.16	52.63	0.00	37.93	8.11	75.68						
Skin cyanosis	yes	1.05	4.21	1.72	6.90	0.00	0.00	2.25	0.134	2.25	0.134	–	–
	no	0.00	94.74	0.00	91.38	0.00	100.00						
Night muscle cramps	yes	11.58	35.79	12.07	44.83	10.81	21.62	26.694	<0.001	24.038	<0.001	2.5	0.114
	no	2.11	50.53	0.00	43.10	5.41	62.16						
Leg heaviness	yes	17.89	29.47	18.97	43.10	16.22	8.11	23.310	<0.001	20.346	<0.001	1.333	0.248
	no	1.05	51.58	1.72	36.21	0.00	75.68						
Walking problems	yes	9.47	7.37	6.90	12.07	13.51	0.00	0.9	0.343	1.778	0.182	0.00	1.00
	no	3.16	80.00	3.45	77.59	2.70	83.78						
Another symptoms	yes	2.11	26.32	1.72	29.31	2.70	21.62	58.368	<0.001	34.225	<0.001	4.00	0.045
	no	2.11	69.47	1.72	67.24	2.70	72.97						

CVI – chronic venous insufficiency.

Table 3. Values of study variables

Parameters	Both groups (n = 95)		CVI group (n = 58)		Control group (n = 37)		Both groups (n = 95)		CVI group (n = 58)		Control group (n = 37)	
	V1	V8	V1	V8	V1	V8	Wilcoxon test	p-value	Wilcoxon test	p-value	Wilcoxon test	p-value
	Me (Q1–Q3)	Me (Q1–Q3)	Me (Q1–Q3)	Me (Q1–Q3)	Me (Q1–Q3)	Me (Q1–Q3)						
VAS [cm]	5.0 (2.0–5.0)	1.5 (0.0–3.0)	5.0 (2.5–5.0)	1.5 (0.0–3.0)	4.0 (2.0–5.0)	1.5 (0.0–3.0)	7.463	<0.001	5.857	<0.001	4.649	<0.001
Saturation on the toe [%]	98.0 (97.0–99.0)	99.0 (98.0–99.0)	98.0 (97.0–99.0)	98.0 (98.0–99.0)	98.0 (97.0–99.0)	99.0 (98.0–99.0)	3.953	<0.001	2.361	0.018	3.309	<0.001
Pulse rate [bpm]	67.0 (63.0–72.0)	69.0 (66.0–71.0)	68.0 (63.0–74.0)	70.0 (67.0–72.0)	67.0 (63.0–71.0)	67.0 (65.0–69.0)	1.793	0.073	1.668	0.095	0.508	0.612
Doppler of reflux (velocity) [cm/s]												
Right popliteal vein	0.2 (0.0–0.3)	0.1 (0.0–0.2)	0.2 (0.0–0.4)	0.1 (0.0–0.2)	0.0 (0.0–0.2)	0.0 (0.0–0.1)	4.838	<0.001	4.308	<0.001	2.201	0.028
Left popliteal vein	0.2 (0.0–0.3)	0.1 (0.0–0.2)	0.2 (0.0–0.3)	0.1 (0.0–0.2)	0.0 (0.0–0.2)	0.0 (0.0–0.1)	4.004	<0.001	3.782	<0.001	1.392	0.164
Right small saphenous vein outlet	0.0 (0.0–0.0)	0.0 (0.0–0.1)	0.0 (0.0–0.0)	0.0 (0.0–0.1)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	1.043	0.297	2.108	0.035	1.400	0.161
Left small saphenous vein outlet	0.0 (0.0–0.0)	0.0 (0.0–0.1)	0.0 (0.0–0.0)	0.0 (0.0–0.1)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.197	0.844	1.090	0.276	1.303	0.193
Right great saphenous vein outlet	0.0 (0.0–0.1)	0.0 (0.0–0.1)	0.0 (0.0–0.1)	0.0 (0.0–0.1)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	1.441	0.150	0.937	0.349	1.274	0.203
Left great saphenous vein outlet	0.0 (0.0–0.0)	0.0 (0.0–0.1)	0.0 (0.0–0.1)	0.0 (0.0–0.1)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.107	0.915	0.429	0.668	0.889	0.374
Right femoral vein	0.2 (0.0–0.4)	0.1 (0.0–0.2)	0.2 (0.0–0.4)	0.1 (0.0–0.2)	0.0 (0.0–0.3)	0.0 (0.0–0.1)	4.574	<0.001	4.019	<0.001	2.374	0.018
Left femoral vein	0.2 (0.0–0.3)	0.1 (0.0–0.2)	0.2 (0.0–0.3)	0.1 (0.0–0.2)	0.1 (0.0–0.3)	0.0 (0.0–0.1)	3.790	<0.001	2.490	0.013	2.971	0.003
Right shin circumference [cm]	38.0 (36.0–40.0)	38.0 (36.2–39.5)	39.0 (37.0–40.0)	38.0 (36.5–39.8)	37.0 (36.0–39.0)	37.0 (36.0–38.0)	1.472	0.141	1.406	0.160	0.423	0.673
Left shin circumference [cm]	38.0 (36.0–40.0)	38.0 (36.0–39.5)	39.0 (37.0–40.5)	38.0 (36.5–39.8)	37.0 (36.0–39.0)	37.0 (36.0–38.0)	1.665	0.096	1.177	0.239	0.825	0.409
Degree of reflux (scale 0–4)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	3.408	<0.001	3.180	0.001	–	–

VAS – visual analogue scale; CVI – chronic venous insufficiency; Me – median; Q1 – 1st quartile; Q3 – 3rd quartile.

in the treatment of CVI. Evidence suggests that isotonic exercises may be an effective method of increasing the hemodynamic performance of the calf muscle pump.[11,12]

Calf-muscle pumping is the primary mechanism to promote blood return from the lower limbs to the heart. During exercise, the calf muscles (gastrocnemius and soleus) contract and compress the deep intramuscular veins, which increases the venous pressure and the blood flow from the deep venous system to the heart. The efficacy of this mechanism depends on talocrural mobility, venous competence and contraction strength of the calf muscles.[13]

To improve venous circulation, researchers have tested different training periods – from 6 weeks to 18 months. Training was planned every day or several times a week, with a duration of each session from 15 min to 1 h. The exercises were performed in the form of walking and stretching and resistance exercises.[14–19] The higher frequency of ankle pump exercises (APE) can effectively promote venous blood return and has anticoagulant effects in the prophylaxis of deep vein thrombosis.[20,21] Based on a study of 29 patients after total hip arthroplasty, Nakayama et al. reported that APE at 60 times/min were more effective than that at 40 or 80 times/min.[22]

So far, no studies have been conducted on training the calf muscles in a sitting position in the form of passive exercises in this group of patients. The purpose of the Bella Vena device is to activate the calf pump by imitating the physiological movement in the ankles (60 times/min). The 8-month period of exercises, despite the unfavorable sitting position, had a positive effect on the venous system. People working in a standing posture are at a significantly greater risk for CVI than those working in a prolonged sitting posture. Ambulatory venous pressure while sitting is about 60–80 mm of water, as opposed to 20 mm while walking, and the number is only slightly higher (about 100 mm) while standing.[23,24]

The innovation of the Bella Vena device is its availability and ease of use at home. The intention of the authors was that anyone in need could use this device at home and exercise several times a day. The objective of the designers was to create a device available to everyone. The Bella Vena device should not be compared to highly technologically advanced robots, but treated as a complement to daily physiotherapy.

In our study, the regularity of training was supervised during monthly visits and telephone consultations by physical therapists. This supervision ensured control of training and gave the opportunity to submit comments on the prototype of the device during its operation. The device itself is easy to use and enables performance of home exercises according to the patient's physical condition.

Limitations of the study

In this study, venous reflux was assessed, but it was not examined how it affects the level of muscle strength and range of motion in the joints, which is important in improving the gait function. Only subjective symptoms of venous insufficiency and the level of venous reflux were assessed. There are no publications in the available literature concerning the use of mechanical devices for supervised passive exercises of the ankle joint at home. For these reasons, the authors could not compare their results with the data of other authors.

Conclusions

Home exercises with the use of a prototype of the Bella Vena device for exercising the lower limb with CVI can improve the calf pump in a group of patients undergoing long-term observation. Such exercises employing an automatic exercise rehabilitation device alleviate the significant symptoms of CVI. Further research must be concentrated on expanding the technological capabilities of the device, which will allow patients to fully engage in exercises based on biofeedback.

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