

Clinical benefits
in patients with peripheral
cardiovascular or vascular pathology
receiving treatment with

happylegs  [®]
the seated walking machine

FUNDSALUD

Health Foundation
Medicine, Science and Society
Zaragoza, october 2014

RATIONALE

There is no doubt that lifestyle and factors known as hygienic-dietetic measures play an important part in treating vascular diseases, along with pharmacological treatment.

As Dr Valentín Fuster recently postulated, the relinquishing of healthy lifestyles is related to an increase in cardiovascular disease and its consequences.

Physical support systems such as the one designed in Happylegs bring benefits due to the importance of preventing sedentary lifestyles. This is not only the case in people with impaired physical mobility, but also in young people who have no time to walk every day.

The interest of our study is focused on the objective documenting of the benefits of systems such as the one developed by Happylegs. This is in accordance with three fundamental sections based on diagnosis and clinical observation. Firstly, the benefits related to blood pressure and all aspects that are connected with cardiovascular protection, evaluating the ABI (ankle-brachial index) which demonstrates the close correlation with vascular risk before and after expose to the Happylegs system.

Secondly, the benefits for the peripheral return circulation, evaluating the symptoms of venous stasis, such as the leg perimeter before and after using Happylegs. Thirdly, an evaluation of the benefits on the locomotor system following treatment with Happylegs in the ankle and knee joints, assessed using a visual pain scale and mobility response.

This study is designed as a pilot study, in the secret hope that it will serve as a basis for more important studies, with a view to objectifying and publishing the benefits of using a therapy such as the one proposed with the Happylegs system.

METHODOLOGY

This is a prospective clinical study for observing the benefits obtained in patients receiving regular passive exercise as opposed to patients receiving the habitual treatment. There will be no pharmacological intervention in either group other than the guided intervention indicated for their pathologies. Furthermore, they will receive the same information regarding treatment based on lifestyle, and in particular, how to avoid sedentary habits.

The patients included in the study will be requested to give their informed consent and their participation or non-participation will in no case lead to any reduction in assistance in normal medical practice conditions.

The first three patients visiting the surgery on odd days with symptoms related to cardiovascular problems, peripheral vascular problems or locomotor system problems in the ankle or knee joint will start a programme of exposure to passive exercise with the Happylegs equipment. On the other hand, those patients visiting the surgery on even days will form the control group.

It would be desirable for the sample estimated in this pilot study to be 20 patients in each of the three pathological categories in the group of patients receiving passive exercise support, and the same number in the controls.

EVALUATION CRITERIA BEFORE AND AFTERWARDS

CARDIOVASCULAR PATIENTS AND PATIENTS WITH PERIPHERAL ARTHROPATHIES

- Ankle-brachial arterial pressure index
- Doppler arterial ultrasound
- Quality of life survey
- Recording of adverse events
- Glucose levels in diabetics

PATIENTS WITH PERIPHERAL VENOUS VASCULAR DISORDERS

- Doppler venous ultrasound
- Leg perimeter
- Quality of life survey
- Glucose levels in diabetics

PATIENTS WITH JOINT PATHOLOGIES

- Ankle and knee perimeter
- Quality of life survey
- Glucose levels in diabetics

OBSERVATION PERIOD

- Six months with clinical evaluation at the start and end of the observation period.
- 60-minute treatment sessions three days a week during the observation period.

PRELIMINARY REPORT

After the first part of the observation period, the clinical benefits are recorded for patients being treated with the Happylegs system, and at an earlier stage in different patient types.

Firstly, patients with a history of peripheral venous insufficiency, with or without a history of prior thrombophlebitis, mentioned an improvement in the symptoms linked with the process in the quality of life survey, such as tired legs, a tingling sensation in the legs and a considerable reduction in inflammation with respect to the ankles and in the calf muscles. This is corroborated by the measurements taken of the leg perimeter before and after this first treatment period.

The second group of patients showing benefits were diabetics, and in particular, those with limited mobility, since their glucose levels before and after the treatment period fell by 6.5% despite being in the initial observation phase.

Likewise, reductions in arterial pressure were observed in treated patients, as well as an improvement in the ankle-brachial pressure index.

With respect to patients with problems in the knee joint, there was improvement in mobility and a reduction in the perception of pain by the patient.

The data contributed by these first results demonstrates the clinical relevance in terms of the favourable evolution of patients receiving treatment compared to those receiving no treatment. It is to be expected that this improvement will increase as the patients' exposure period progresses.

It can thus be concluded that the use of the Happylegs system brings about an improvement in the treatment received by the patients, and therefore an improvement in the evolutionary prognosis of those patients should be expected.

RESULTS

BEHAVIOUR OF BASELINE GLUCOSE LEVELS UNDER FASTING CONDITIONS.

Patients receiving active treatment with the Happylegs showed an average reduction in glucose levels of 15% with respect to the baseline parameters after the observation and treatment period, compared with patients receiving only hygienic and dietetic advice and habitual medical treatment.

There is no doubt that this reduction could be greater if there is an increase in the daily period of use of the system over that implemented during the study, for logistical and methodological reasons. The necessary medical treatment could even be corrected for diabetes mellitus with the ensuing economic savings in drugs.

Passive mobilisation with the Happylegs system achieves an increase in glucose consumption by the muscles of the lower limbs, which is consolidated by the increase in the outgoing and returning blood flow activated during treatment.

BEHAVIOUR OF THE ARTERIAL PRESSURE AND ANKLE-BRACHIAL PRESSURE INDEX

The ankle-brachial index is a diagnostic tool used to evaluate the blood circulation to the lower extremities. This parameter compares the systolic ankle artery pressure (in the posterior tibial artery and dorsalis pedis artery) to that of the brachial arteries (humeral arteries).

The ankle-brachial index is a widely-used tool for the non-invasive evaluation of peripheral vascular disease. Studies have shown that ABI Sensitivity (epidemiology) is 90% with a Specificity (epidemiology) of 98% in detecting haemodynamically significant stenosis (serious) >50% in the large arteries of the lower limbs, defined by angiography.

VALUE OBTAINED	INTERPRETATION
> 1.2	Abnormal
1.0 - 1.2	Normal
0,9 - 1.0	Acceptable
0.8 - 0.9	Arterial disease
0.5 - 0.8	Moderate arterial disease. Claudication may develop with values below 0.6
< 0.5	Severe arterial disease, rest pain if <0.25

In the group of patients using the Happylegs system, there was an increase in the ankle-brachial index, indicating an improvement, especially in the arterial flow of the lower extremities and consequently a reduction in global vascular risk.

Likewise, an improvement is expected in the behaviour of glucose levels and the stabilisation of arterial pressure values as the time of exposure to the equipment is increased.

BEHAVIOUR OF VENOUS RETURN CIRCULATION IN LOWER LIMBS

The benefit of active mobility (both active mobilisation and passive mobilisation of the lower limbs) on the venous return circulation is already well known. Therefore the behaviour of patients using the Happylegs system was predictable in this respect.

We used several systems to evaluate the efficacy of the physical therapy treatment provided through the tested system. Firstly, the visual comfort scale of between 1 and 10, which the patients had to complete before starting, halfway through the observation period and at the end of that period. An evaluation was made of the heavy sensation, numbness or tingling and pain in feet, ankles and legs. An improvement was observed in all the parameters of the symptoms related to venous stasis in people with poor return circulation.

In this respect, a difference should be established between patients maintaining autonomy with respect to mobility and patients with impaired mobility due to all manner of processes, especially those affecting the locomotor system. In these patients, in which the perception of wellbeing was greater, since their disability was vastly improved by the passive mobilisation of the Happylegs system and in a similar way to the above cases, it is to be expected that the longer the exposure to the system, the greater the level of wellbeing.

In patients mentioning or presenting a history of phlebitis or thrombophlebitis in the calf area, the leg perimeter was measured with a tape measure and at the end of the exposure period, the average reduction obtained was 9% less than during the initial baseline phase.

It can be concluded that both therapeutic aspects and preventive aspects intervene with respect to peripheral venous disease in the lower extremities with the continuous use of the Happylegs system.

BEHAVIOUR OF THE LOCOMOTOR SYSTEM

Patients with a documented history of arthrosis in the knee and ankle joints were evaluated.

Patients who, apart from receiving hygienic and dietary advice and the habitual medical treatment, received treatment with Happylegs showed a significant improvement in quality of life and in visual pain scale, with an improvement in functional joint capacity being perceived, especially in the knees. Likewise there was a reduction in the joint perimeter in the knees at the level of the intrameniscal ligament and in the ankle at the level of the perimeter between the lateral and medial malleolus.

The explanation of these clinical changes is two-pronged. Firstly, the mechanical aspect due to the passive mobility of the joint and thus the benefit on the joint capsule, and the synovial fluid flow within the joint. And secondly, the obvious benefit of stimulating the return and outgoing flows in the limb, as the cells and proteins for joint repair are supplied by the bloodstream. So much so, that during the 1980s, Soviet traumatology was responsible for designing the functional plaster for reducing movement in fracture zones as, if there was joint mobility above and below it, recovery was much faster and the only explanation for this lay in the bloodstream which provided the necessary instruments for recovery and in certain cases, cure.

CONCLUSIONS

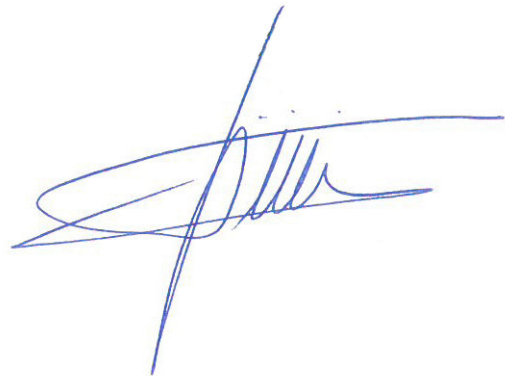
In the light of the evolution of the different patients observed in this study, including those not using the Happylegs system and those receiving this therapy, we can conclude that regular, continuous use of passive systems for mobilising the lower extremities and in particular, the Happylegs system, generate an improvement in different variables in the people using them, with no side-effects of any kind or risk in use, given that during the study, no harmful effects with respect to the patients were reported or observed.

The explanation for the patient improvement phenomena observed in the different fields apart from the placebo effect lies in the activation of the blood circulation brought about by the Happylegs system in the people using it. There is no doubt that the constant and continued use of the system for several hours on a daily basis produces an increase in the improvement and a favourable evolution of the lesions.

We cannot rule out the possibility of this circulatory activation having a positive influence on other pathologies of the body, apart from those analysed in greater depth in our study.

In fact, testimonies by patients about improvements in cognitive abilities and in general organic functionality, including greater personal autonomy, have presented us with the challenge of continuing our studies beyond the lower extremities and extending them to the cognitive and emotional behaviour of patients with cognitive deterioration and early signs of dementia and, in particular, those of vascular origin.

Zaragoza, April 2015
Dr Javier Tisaire Sánchez
Clinical Research Area Coordinator
FUNDSALUD Health Foundation
Medicine, Science and Society

A handwritten signature in blue ink, appearing to be 'Javier Tisaire Sánchez', written over a horizontal line.

MEASUREMENTS IN 20 PATIENTS

GLYCAEMIA mgrs/dL

	BASAL	SIX MONTHS
1	136	117
2	100	98
3	128	116
4	96	84
5	140	112
6	92	93
7	88	82
8	134	128
9	148	134
10	156	134
11	90	86
12	87	91
13	84	80
14	136	123
15	112	106
16	100	101
17	98	
18	124	112
19	126	124
20	130	111

CONFORT SCALE

BETWEEN 1 to 10 / NO HEAVINESS IN LEGS to EXTREME HEAVINESS

	BASAL	SIX MONTHS
1	9	5
2	9	4
3	9	4
4	8	6
5	9	7
6	6	3
7	7	2
8	9	3
9	9	6
10	10	4
11	7	2
12	9	4
13	6	3
14	5	1
15	8	5
16	9	8
17	6	4
18	6	4
19	10	7
20	7	2

COMFORT SCALE

BETWEEN 1 and 10 / NO PAIN to VERY PAINFUL

	BASAL	SIX MONTHS
1	7	4
2	5	1
3	9	5
4	6	2
5	8	5
6	6	3
7	4	1
8	8	8
9	9	7
10	7	6
11	5	2
12	8	3
13	6	5
14	4	4
15	8	4
16	7	5
17	6	
18	9	7
19	3	3
20	8	6

ANKLE / BRACHIAL PRESSURE INDEX

	BASAL	SIX MONTHS
1	1,1	1,2
2	1	1
3	1,2	1,2
4	0,9	1
5	1	1
6	0,8	0,9
7	1,1	1
8	1	1
9	1,2	1,2
10	1	1
11	0,8	0,8
12	1,1	1,2
13	0,7	0,9
14	0,8	0,8
15	0,9	1,1
16	1	1
17	1,2	
18	1	1
19	1,1	1,1
20	0,8	0,9

CALF PERIMETER (cm.)

	BASAL	SIX MONTHS
1	52	48
2	46	38
3	50	45
4	38	36
5	48	43
6	57	53
7	50	45
8	49	44
9	35	35
10	48	45
11	49	44
12	58	52
13	39	37
14	51	50
15	46	40
16	49	43
17	32	31
18	30	30
19	47	44
20	44	41

ANKLE PERIMETER (cm.)

	BASAL	SIX MONTHS
1	22	21
2	24	22
3	21	21
4	28	25
5	19	17
6	23	22
7	18	18
8	20	19
9	15	15
10	17	17
11	22	20
12	25	21
13	29	25
14	24	23
15	28	27
16	23	23
17	23	21
18	21	20
19	27	25
20	19	19

KNEE PERIMETER (cm.)

	BASAL	SIX MONTHS
1	44	42
2	48	45
3	40	38
4	36	35
5	41	38
6	47	44
7	34	30
8	40	38
9	35	35
10	39	38
11	46	44
12	44	43
13	38	36
14	35	34
15	39	39
16	48	45
17	44	42
18	42	41
19	45	41
20	39	37



2018

CERTIFICATE OF REGISTRATION

This certifies that:

AUTOERGON 2002, S.L.
Lentisco, 11-Poligono Empresarium
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Zaragoza Zaragoza, SPAIN 50720

is registered with the U.S. Food and Drug Administration for FY 2018 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	3010866094
DUNS No.:	46-282-4181
Proprietary Name:	Happylegs, Happy Legs
Device Classification Name:	EXERCISER, POWERED
Product Code:	BXB
Regulation Number:	890.5380
Official Correspondent and U.S. Agent:	Registrar Corp 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

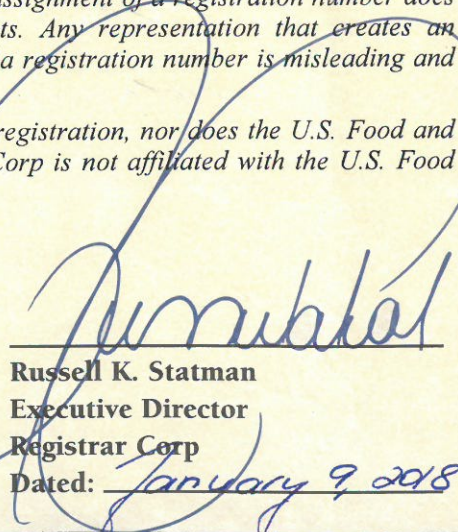
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Russell K. Statman
Executive Director
Registrar Corp

Dated: January 9, 2018

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ACTA DE COMPROMISO

Con esta firma asumimos la responsabilidad de mantener los valores de sostenibilidad, respeto por el medio ambiente y por las personas.

De acuerdo con los objetivos de Feniss, nos comprometemos a mantener nuestra empresa libre de obsolescencia programada, con innovación sostenible, así como a trabajar activamente y hacer públicas las acciones concretas que configuran nuestra contribución a la sociedad.

Barcelona, 28 de Mayo de 2016

Nombre de la organización Autoergon 2002 S.L.

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18005 GRANADA

Dr. med. JORGE ULLOA IPARRAGUIRRE
Cardiologist
Practitioner No. 181801698

As a cardiologist, I have been recommending Happylegs for some time to patients aged between 60 and 65, because at this age the use of an exercise bike is no longer advisable owing to knee-related problems. Also, treadmills take up a lot of space and are very expensive.

For females, who have less time, which is split between their working day and household chores, leaving them with almost no time to go out walking, the alternative when sitting is to use Happylegs. By sitting and using this platform for a number of hours, I have noticed that a weight loss of about 2 kg can be obtained and good health can be maintained. Joint pain and swelling in ankles and legs is reduced as is heaviness and tingling sensations

Happylegs is an excellent tool to activate arterial and venous circulation and force the heart to pump more blood and thus increase the rate of circulation. This will prevent arteriosclerosis, although it should be complemented with a Mediterranean diet, blood pressure monitoring, comprehensive analyses and an ECG and Doppler echocardiography every 6 months

In my patients I have also seen a great improvement in cardiac functions. Many of them have gone from a contractility expressed as an ejection fraction (EF) of 46-48% to 56-62% (normal is anything above 55%).

It is important not to limit the number of hours of use of Happylegs. Do not only use for 10 minutes, as recommended by physiotherapists, but the maximum time that you have to sit and read, listen to music or watch TV.

I would also like to point out that most patients have fallen into the routine of no longer going out for walks, with the resulting weight gain, pain in hips, knees and ankles. For some, walking is a mission impossible as they suffer from vertigo or Parkinson's or they have a "fear of going outside" caused by accidents or falls in the street.

In short, I can confirm that this is a great tool to maintain good physical shape without secondary effects and with demonstrated effectiveness in my patients.



Dr. JORGE ULLOA IPARRAGUIRRE
Coleg. Nº 181801698
CARDIOLOGÍA

Granada, 22 March 2013

Therapeutic studies back the effectiveness of Happylegs

The good functioning of the return circulation is fundamental for blood to reach the heart. This fluid contains toxic substances and its mission is to carry out the biological interchange which is to eliminate CO₂, urea and waste material, which are the final product of tissue metabolism ("garbage" produced by normal cellular functioning). Once this cleansing process has finished, the oxygen enriching process starts in the lungs and the blood is then transported to the heart and from there distributed throughout the body via the arterial system.

When the systems that favour this return break down, it causes edema in the lower limbs and leads to ideal conditions that cause chronic venous insufficiency, which is manifested in the form of varicose veins.

The factors which favour the return are perfectly known: *vis a tergo*, *vis a fronte*, muscular pump of the calf, valve system, venous tone and pulsation of neighbouring arteries. There is, however, another system which I consider to be of great physiological importance. I am referring to Lejars sole sponge.

In the return physiology, besides the centripetal, aspiration or propulsion forces, there exists another which acts as an injection pump adjacent to the central venous column, whose outer network resides precisely in the sole venous squashing.

The Lejars sponge is a dense intradermal and subdermal venous network. Anatomically, the front part flows into the subcutaneous sole arch; the side part into the back veins and the back part into the retromolar and achilles arches. This system plays an important part in the physiology of the venous drainage of the feet.

One walks on a sponge, which is squashed with each step. When walking, the intermetatarsal spaces and the aponeurotic sheath undergo an alternating dilation and contraction process which corresponds to the pressure exerted on the venous cushion from the osteomuscular sole of the foot. This process implies a dilation of the perforating veins and the emptying of the deep veins of the feet due to the blood propulsion effect.

From a practical point of view, and keeping in mind the importance that the Lejars injection system has to the return physiology, it is logical to research new ways to improve it. In this regard, Mr Gálvez, an enthusiastic researcher from Aragon, has devised a machine called HAPPYLEGS, whose mechanism consists of directly applying pressure to the sole sponge, thereby increasing the flow of the venous system in the feet. The effect is similar to passive exercise which forces the feet to carry out a constant exercise of extensions and contractions.

I consider that this device will be of great benefit to all those people who lead a sedentary lifestyle, who suffer from chronic venous insufficiency or varicose veins, who suffer from classic venous ailments, and finally those who have insufficient calf venous pumping, which is often the cause of thrombosis.



Study carried out by Dr. M.A. Santos Gastón
VASCULAR SURGEON - PHLEBOLOGIST
President of EspreV
(Foundation for the Study and Prevention
of Veinous Diseases)

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