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The effectiveness of a novel neuromuscular electrostimulation method versus intermittent pneumatic compression in enhancing lower limb blood flow

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Objective: **This study compares the effectiveness of a neuromuscular electrostimulation device (geko T-1; Firstkind Ltd, High Wycombe, UK) in enhancing lower limb blood perfusion with two leading intermittent pneumatic compression (IPC) devices, the Huntleigh Flowtron Universal (Huntleigh Healthcare Ltd, Cardiff, UK) and the Kendall SCD Express (Covidien plc, Dublin, Ireland). The subjects' tolerance of the devices was also compared.**
Methods: **Ten healthy subjects were recruited. The devices were fitted bilaterally, in a sequential manner, for 30 minutes. Ultrasound and laser Doppler fluxmetry assessments were performed.**
Results: **The geko T-1 device was superior to both IPC devices in increasing both venous and arterial blood volume flow by ~30% (95% confidence interval [CI], 23.7%-82.4%; $P \leq .001$). The geko T-1 increased arterial blood velocity by 24% (95% CI, 9.7%-24.5%; $P \leq .001$). A substantial increase in the total microcirculatory blood velocity by ~370% (95% CI, 13.5%-39.7%) was reported after the use of the geko T-1 ($P \leq .001$). With use of the visual analog scale, no significant differences in discomfort were found between the geko T-1 device and the IPC devices ($P > .05$).**
Conclusions: **The geko T-1 device is more effective than the IPC devices in increasing venous, arterial, and microcirculatory blood velocity. The devices studied were safe and well tolerated by healthy subjects. (J Vasc Surg: Venous and Lym Dis 2014;2:160-5.)**

Mechanical prophylaxis for the prevention of deep venous thrombosis (DVT) enjoys wide popularity, as its use is not associated with the adverse events seen with pharmacologic prophylaxis.[1] Intermittent pneumatic compression (IPC) is one of the most commonly used. All IPC devices have the same general objective: limb compression to expel blood from the underlying superficial and deep veins.[1]

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Another method for the prevention of DVT is direct electrical stimulation of the lower limb muscles, which has also been shown to be effective in improving blood flow.[2-4] Electrical stimulation has also been shown to reduce the incidence of DVT at least as well as other forms of mechanical compression do.[5-8] However, the level of discomfort associated with electrical stimulation has until recently limited the application of such techniques in clinical practice. A novel neuromuscular electrostimulation device (geko T-1) has been developed by Firstkind Ltd (High Wycombe, UK) to provide the benefits of electrical stimulation but without the previously associated discomfort. The system operates by use of OnPulse Technology, activating the calf and foot pumps of the leg by low-intensity neuromuscular electrical nerve stimulation of the common peroneal nerve located in the region of the popliteal fossa.[9] This study compares the effectiveness of geko T-1 at threshold and normal clinical use settings in enhancing lower limb blood perfusion with two leading IPC devices: Huntleigh Flowtron Universal (Huntleigh Healthcare Ltd, Cardiff, UK) and Kendall SCD Express (Covidien plc, Dublin, Ireland). Furthermore, subjects' tolerance and acceptance of the devices were compared by a discomfort questionnaire.

METHODS

Subjects. Ten healthy volunteers, aged between 18 and 65 years, were recruited to participate in the study. The study was approved by the North London Research

Ethics Committee 1 (reference 05/Q0408/14). The specific inclusion and exclusion criteria are presented in the Table.

Study design. All examinations were performed in a room in which the temperature and humidity were controlled (24° ± 1° C; relative humidity, 30%-40%). Subjects clad in shorts lay supine on a table with the head supported by a pillow and tilted upward to 45°. After 30 minutes of supine rest, baseline measurements including blood flow and volume together with microcirculatory velocity were made by color-flow duplex ultrasound examination at the femoral artery and superficial femoral vein (Philips IU22; Philips Healthcare, Andover, Mass) and by laser Doppler fluxmetry at the dorsum of the foot (Laser Doppler Perfusion and Temperature Monitor DRT4; Moor Instruments Ltd, Axminster, UK). Test devices were then fitted bilaterally by the clinical investigator to the subject's legs, in accordance with the manufacturer's instructions, in a sequential manner. As the interventions involved the use of mechanical devices, it was not possible to blind the participants or the investigators. To reduce bias, the order of the device tested was made in accordance with a pre-set balanced randomization schedule prepared by the clinical investigator. On the basis of previous findings, each device was active for a period of 30 minutes followed by a 10-minute recovery phase to allow vascular re-equilibration before application of the next device.[9] At the end of each program and while the devices were still active, measurements performed at baseline were repeated. The devices were fitted to five subjects in the following order: geko T-1 normal clinical use setting, geko T-1 threshold setting, Huntleigh Flowtron Universal (IPC-HF), and Kendall SCD (IPC-Kendall). The order of the devices was changed with the remaining five subjects (IPC-HF, IPC-Kendall, geko T-1 normal clinical use setting, and geko T-1 threshold setting).

After each program, subjects were asked to evaluate their acceptance and tolerance of each device by a discomfort questionnaire. Discomfort was compared with a blood pressure cuff inflated around the upper arm, where blood pressure was assessed as the highest score, because the discomfort for the geko device is known to be minimal from previous studies. Subjects rated their discomfort levels with a visual analog scale by marking the level of the perceived pain along a 100-mm line, marked at one end "no sensation" and at the other end "severe discomfort." A discrete five-category verbal rating scale was also used to select the appropriate category of the perceived discomfort: 1, no sensation (other than muscle tensing and relaxing); 2, minimal sensation; 3, mild discomfort; 4, moderate discomfort; or 5, severe discomfort. At the end of the assessments, the subject's deep veins were re-examined with duplex ultrasound to exclude the development of DVT.

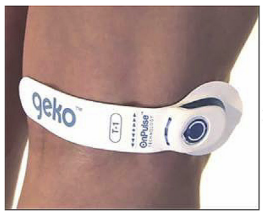

Fig 1. Geko T-1 device specifications.

Transcutaneous electrical nerve stimulation was performed with a novel device (geko T-1; Fig 1). The geko T-1 device is a small, disposable, internally powered, self-adhesive system that is applied over the common peroneal nerve (also called the lateral or medial popliteal nerve) located in the region of the popliteal fossa. This nerve innervates the lower limb musculature; the stimulation causes isometric contraction of several muscles in the lower limb, resulting in enhanced venous return.[9] The device has seven stimulation settings relating to pulse width ranging from 70 to 560 µs, set by the on-off switch and indicated by a flashing light (setting 1, lowest; setting 7, highest). The device operates at a fixed frequency (1 Hz) with a constant

Table. Subject inclusion and exclusion criteria

Inclusion criteria	
Health	Good general health
Age	Between 18 and 65 years
Medical history	No abnormal findings; absence of DVT and hematologic disorders
BMI	Between 18 and 34 kg/m^2
ABPI	Normal ABPI > 0.9
Drugs	No history of drug abuse (including alcohol)
Medication	No medication during 30 days preceding or during the study
Exclusion criteria	
Health	Organ dysfunction, any clinically significant deviation from normal in the physical determinations
Age	<18 years or >65 years
Medical history	Hematologic disorders, previous DVT or pulmonary embolism, varicose veins or lower limb ulceration, musculoskeletal disorders, recent surgery, and recent trauma to lower limb; history of gastrointestinal, hepatic, renal, cardiovascular, endocrine, neurologic, dermatologic, rheumatologic, metabolic (including diabetes), psychiatric, or systemic disease
BMI	Chronic obesity (BMI >34 kg/m^2)
ABPI	Peripheral arterial disease (ABPI <0.9)
Medication	Any medication in the previous 30 days

ABPI, Ankle-brachial pressure index; *BMI,* body mass index; *DVT,* deep venous thrombosis.