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# The effect of a novel electrical stimulation method for improving lower limb blood flow in healthy volunteers

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Page 4 of 265 Abstract Venous Thromboembolism (VTE) is a significant preventable complication that causes morbidity and mortality not only in hospitalised patients, but also in healthy individuals. Pharmacological and mechanical prophylactic methods are available. Pharmacological methods, although are effective in reducing the incidence of VTE, the bleeding risk associated with their use is a major drawback. Besides pharmacological methods, clinical practice guidelines also recommend the use of mechanical methods (NICE, 2010b). The rationale for using mechanical methods is to increase venous return and decrease the risk of venous stasis, one of the compounding factors for VTE. As with pharmacological methods, mechanical interventions are also associated with side effects. Electrical stimulation is an alternative method, which has been shown to be effective in improving blood flow (Faghri et al., 1997, Lindstrom et al., 1982, Nicolaidis et al., 1972). This method however, has not gained widespread use mainly due to the elevated discomfort associated with its use at high intensities. The limited number of available electrical stimulation devices, are complex in structure and restricts mobility. Therefore, developing an alternative technique that is effective and easy to use is justifiable. It is among our intentions in the studies presented in this thesis, to investigate the effectiveness of a novel electrical stimulation technique. The studies outlined in this thesis were carried out on healthy adult volunteers, with the intention of investigating the efficacy of a custom built neuromuscular electrical stimulation device (THRIVE) in enhancing lower limb blood flow and supporting the development of a prototype to a commercial medical device (geko™ T-1). The device activates foot and calf muscle pumps of the lower leg using OnPulse™ Technology; a software that ensures safe and controlled delivery of electrical impulses. The effect of the novel device on cardiac function was initially investigated, where the electrical stimulation device was applied bilaterally for 30 minutes at two pulse width settings 400µs and 600µs on 10 healthy subjects lying supine. A significant difference in cardiac output was reported following echocardiography assessments,  $p \leq 0.05$ . Similarly, a significant increase in skin microcirculatory velocity together with arterial peak velocity and blood volume flow was reported,  $p \leq 0.05$ . Further investigations were then performed on 10 healthy subjects seated in an airline seat for a period of 4 hours, to explore the systemic effect of the electrical stimulation device applied for a period of 5 minutes on specific blood coagulation parameters. A series of lower limb circulatory dynamic assessments were performed at baseline and at 1, 2, 3 and 4 hours. Blood coagulation parameters and blood clotting time were measured through analysis of blood withdrawn from three anatomical sites (arm, right leg and left leg). Results obtained have shown a highly significant increase in lower limb blood perfusion,  $p \leq 0.001$ . An enhanced fibrinolytic activity, characterised by a significant drop in tissue plasminogen antigen levels was seen. No major effects on vital signs were reported. Finally, a comparison of the effectiveness of the novel device with two leading mechanical prophylaxis devices, Huntleigh Flowtron™ Universal and Kendall SCD™ was performed on 10 healthy subjects. Each device was fitted for a period of 30 minutes followed by a 10 minute recovery phase, in a sequential manner. Colour flow Doppler ultrasound in addition to skin microcirculatory and vital