A Comparative Study Investigating the Effectiveness of the geko™ Medical Device versus Intermittent Pneumatic Compression in Enhancing Lower Limb Blood Flow in Healthy Subjects

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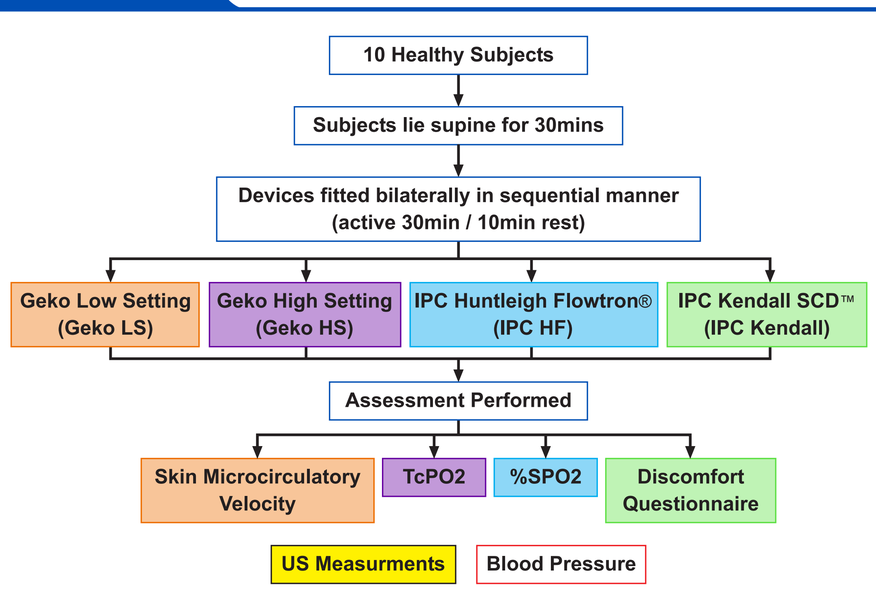
Introduction

Mechanical prophylaxis for the prevention of deep vein thrombosis (DVT) has enjoyed wide popularity, as its use is not associated with the adverse events seen with the pharmacological prophylaxis. Intermittent pneumatic compression (IPC) is an effective form of mechanical prophylaxis [1]. geko™ is a novel medical device developed that activates the venous pumps of the calf and foot, via low> intensity transcutaneous electrical nerve stimulation of the common peroneal nerve located in the popliteal fossa [2, 3].

Aims

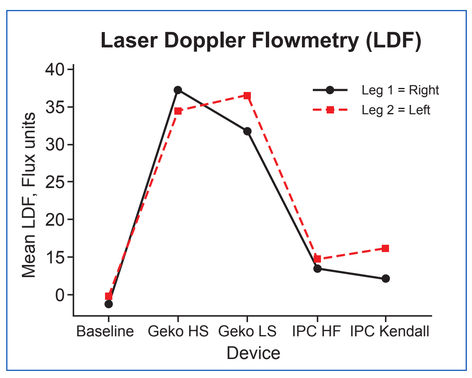
The study compares the effectiveness of the geko™ device in enhancing lower limb blood perfusion with two leading IPC devices, Huntleigh Flowtron® Universal and Kendall SCD™. Subjects' tolerance and acceptability to the devices were also compared using visual analogue scale and verbal rating score.

Methodology



Results

Laser Doppler Flowmetry

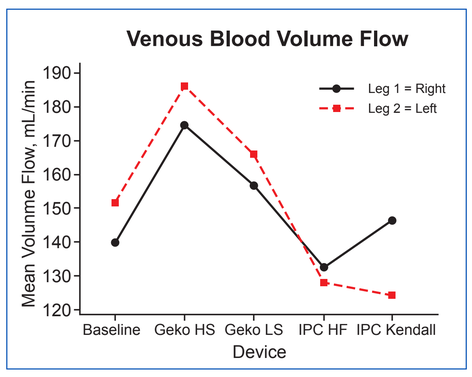


geko™ is significantly more effective than IPC devices in increasing microcirculatory blood velocity. Percentage change compared to baseline was 394% with Geko HS, 345% Geko LS, 44% IPC HF 59% IPC Kendall.

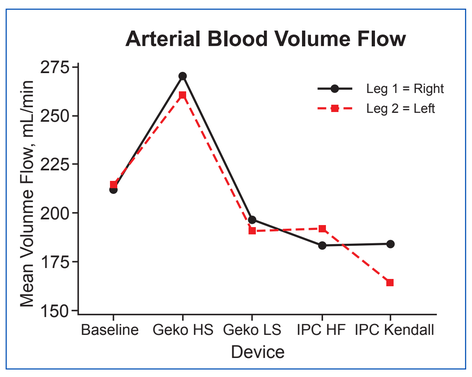
Ultrasound Measurements

Blood Volume Flow

Highly significant difference was found between the devices, p≤ 0.001.



Percentage change compared to baseline was 33% with geko HS, 14% Geko LS, -4% IPC HF and Kendall.



Percentage change compared to baseline was 30% with geko HS, -7% Geko LS, -9% IPC HF and -16 % with IPC Kendall.

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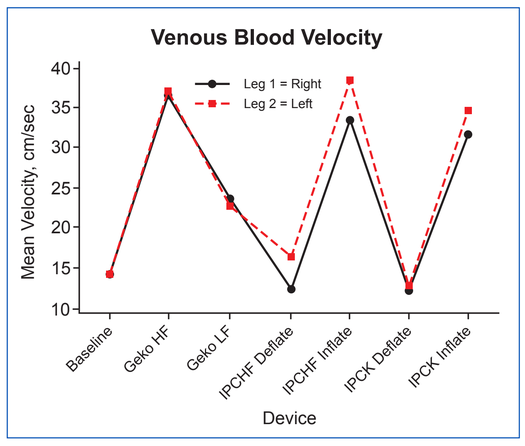
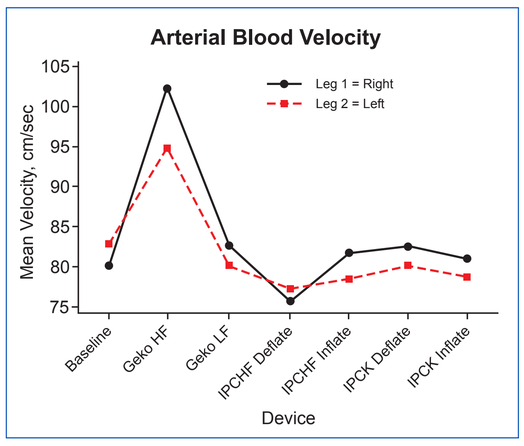
Results continued

Blood Velocity

Highly significant difference was found between the devices, p≤0.001. Measurements for the IPC were made during the inflation and deflation period, and the geko accelerates every second, while IPC accelerates once per minute.



Percentage change compared to baseline was 174%with geko HS, 73% geko LS, 166% IPC HF inflate, 11% IPC HF deflate, 143%IPC K inflate,-9% IPCK deflate.



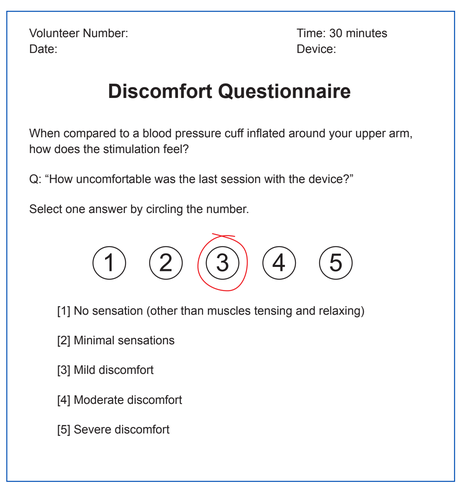
Percentage change compared to baseline was 24%with geko HS, 2% Geko LS, -0% IPC HF inflate, -4% IPC HF deflate, -1%IPC K inflate, 1% IPCK deflate.

Safety Measurements

Blood pressure, heart rate, transcutaneous tissue oxygen (TcPO2) and Tissue oxygen saturation (%SPO2) were all stable throughout the study. No differences were found between devices, p > 0.05.

Discomfort Questionnaire

Both the IPC devices studied and geko™ are well tolerated by healthy subjects. Rates are mainly up to VRS 3 = mild discomfort. Discomfort was higher with the geko™ as compared to IPC p ≤ 0.05 when using verbal rating score (VRS) following short term usage.



Volunteer Number: Time: 30 minutes
Date: Device:

Discomfort Questionnaire

When compared to a blood pressure cuff inflated around your upper arm, how does the stimulation feel?

Q: "How uncomfortable was the last session with the device?"

Select one answer by circling the number.

1 2 3 4 5

[1] No sensation (other than muscles tensing and relaxing)

[2] Minimal sensations

[3] Mild discomfort

[4] Moderate discomfort

[5] Severe discomfort

Conclusion

The study suggest that geko™ device is superior to the IPC devices in enhancing microcirculatory blood flow together with blood volume flow and arterial blood velocity in the lower limbs. An equivalent increase in venous velocity was observed with both the geko™ device and IPCs. Both the IPC devices studied and the geko™ were well tolerated. Further, no significant changes in mean vessel diameters, or vital signs were found throughout the study.

References

[1] Kakkos, S.K., et al., Combined intermittent pneumatic leg compression and pharmacologica prophylaxis for prevention of venous thromboembolism in high-risk patients. Cochrane Database Syst Rev, 2008(4): p. CD005258.

[2] Tucker, A., et al., Augmentation of venous, arterial and microvascular blood supply in the leg by isometric neuromuscular stimulation via the peroneal nerve. Int Angiol, 2010. 19(1): p. e31-37.

[3] Jawad, H., et al., The effect of OnPulse In Improving Lower Limb Blood Flow In Healthy Volunteers, 2011: Prakt.Flebol. p. 41.

geko™ circulation support