

MULTICENTER TRIAL OF INTERMITTENT PNEUMATIC COMPRESSION FOR LOWER LIMB CIRCULATION IN HEALTHY ADULTS

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BACKGROUND

Sequential Intermittent pneumatic compression (IPC) enhances venous return, increases blood flow velocity, and reduces edema through sequential external pressure.¹⁾ To our knowledge, no study has simultaneously evaluated IPC-induced changes in femoral vein hemodynamics using duplex ultrasound together with objective edema-related parameters and pain in healthy adults. This study aimed to evaluate the efficacy and safety of sequential IPC on hemodynamics, edema, and pain.

METHODS

- **Study design:** Prospective, multicenter, open-label, single-arm trial
- **Participants:** 60 healthy adults (mean age 61.8 years) without deep vein thrombosis
- **Intervention:** Sequential 4-chamber IPC using CGM MBA-1701 (Ceragem, Korea), applied bilaterally (36 minutes, twice daily for 10 days)
- **Assessments:** Conducted at baseline, Day 1, Day 5, and Day 10
- **Outcome measures:**
 - **Primary:** Femoral vein PSV, AP diameter, CSA(duplex US)
 - **Secondary:** Limb volume(3D scanner), Circumference, Edema Index(ECW/TBW), Pain(VAS), BMI
- **Statistical analysis:** Repeated-measures ANOVA

Abbreviations: PSV, peak systolic velocity; AP, anteroposterior; CSA, cross-sectional area; ECW/TBW, extracellular water/total body water; VAS, visual analog scale; BMI, body mass index.

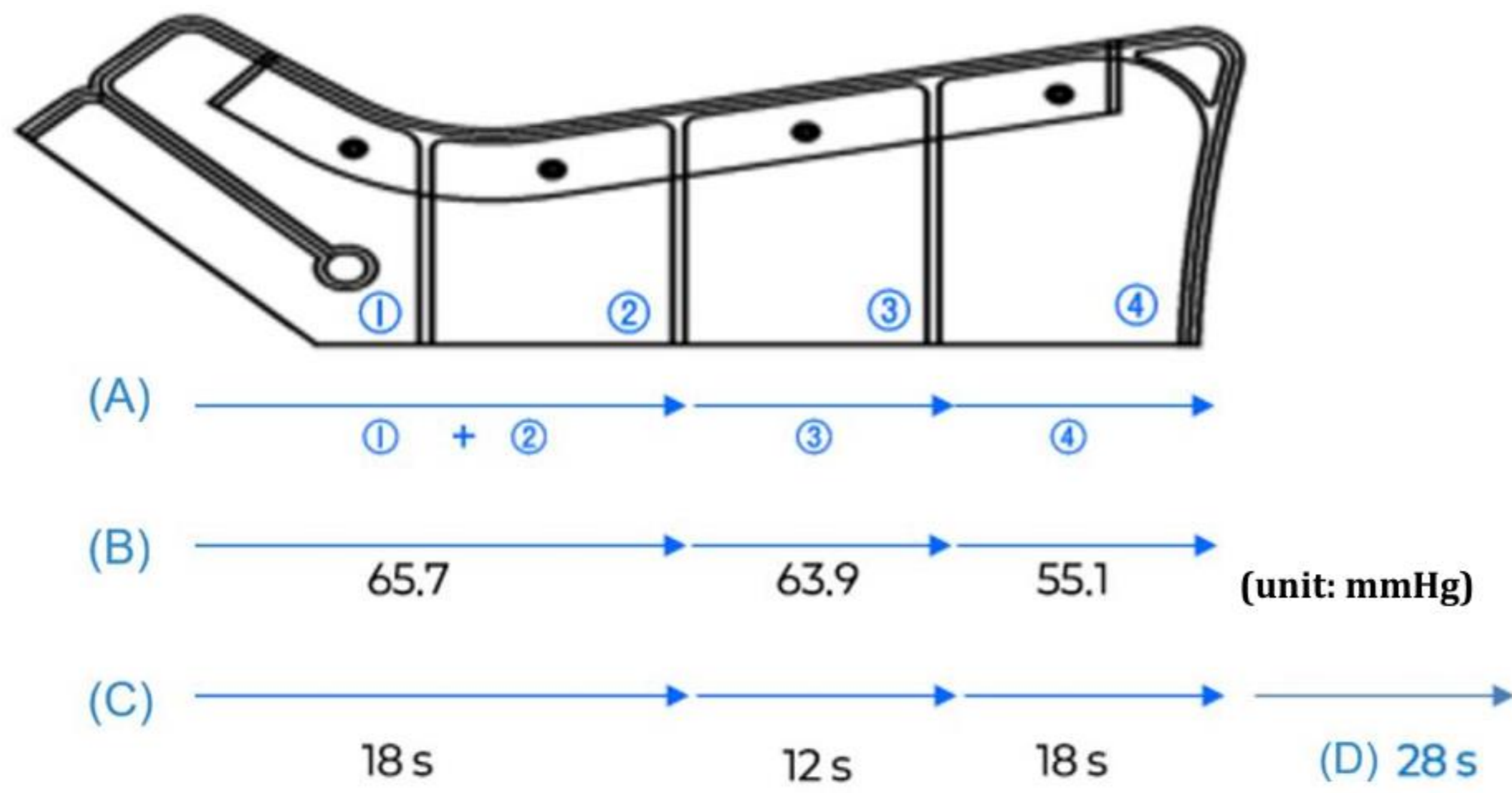


Figure 1. Sequential compression protocol of the IPC device across four chambers.

(A) Compression sequence; (B) chamber pressure; (C) inflation time; (D) decompression phase. Distal-to-proximal inflation (65.7→55.1 mmHg, 76 s cycle) generates a pressure gradient, enhancing venous return via a muscle pump-like mechanism.

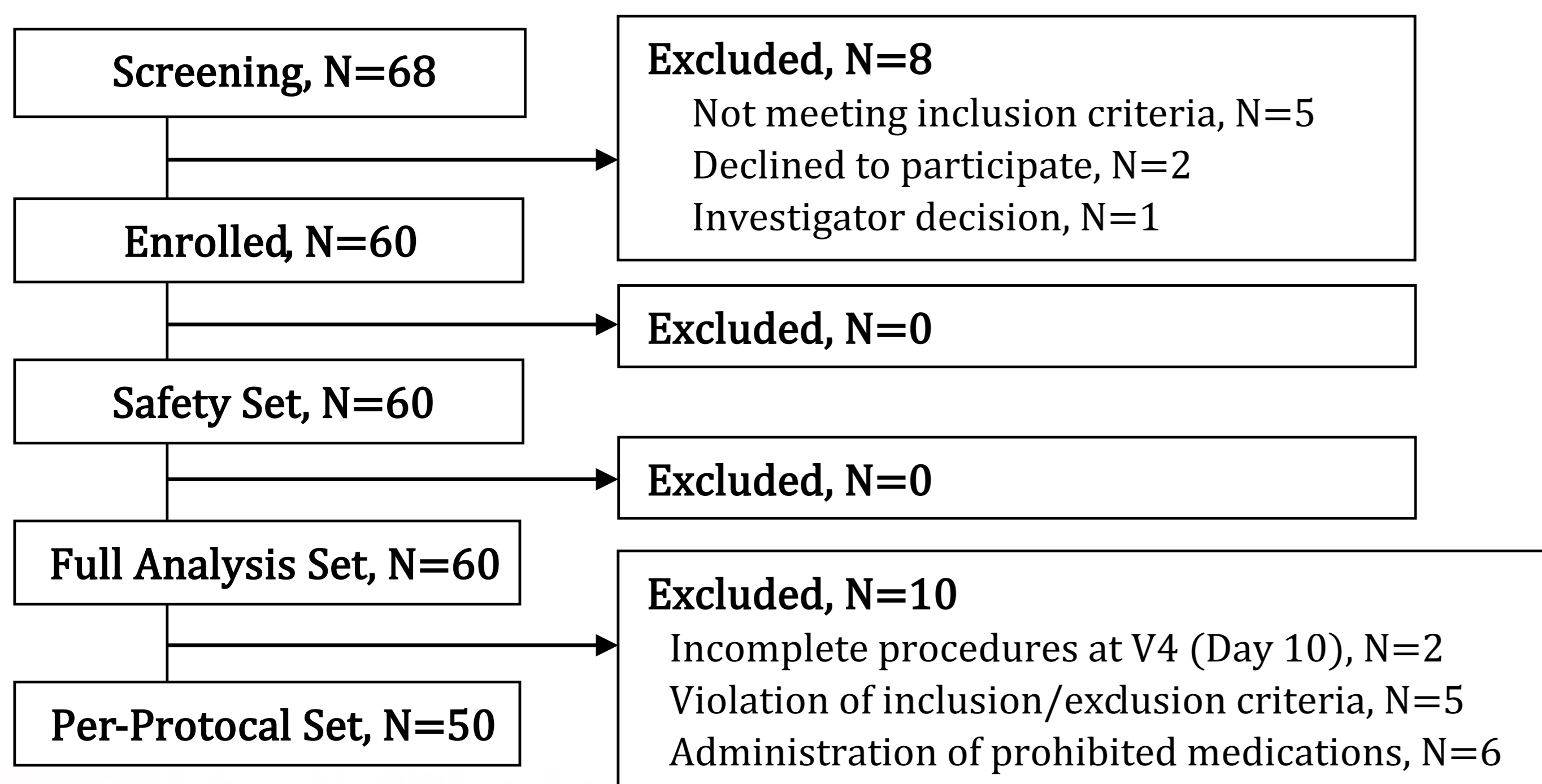


Figure 2. Diagram of participant disposition throughout the trial.

For reasons of exclusion from the Per-Protocol Set, some subjects were counted multiple times as they met multiple exclusion criteria.

Reference ¹⁾ Y. Christen, R. Wütschert, D. Weimer, P. de Moerloose, E. K. O. Kruihof, and H. Bounameaux, "Effects of intermittent pneumatic compression on venous haemodynamics and fibrinolytic activity," Blood Coagulation & Fibrinolysis, vol. 8, no. 3, 1997.

RESULTS

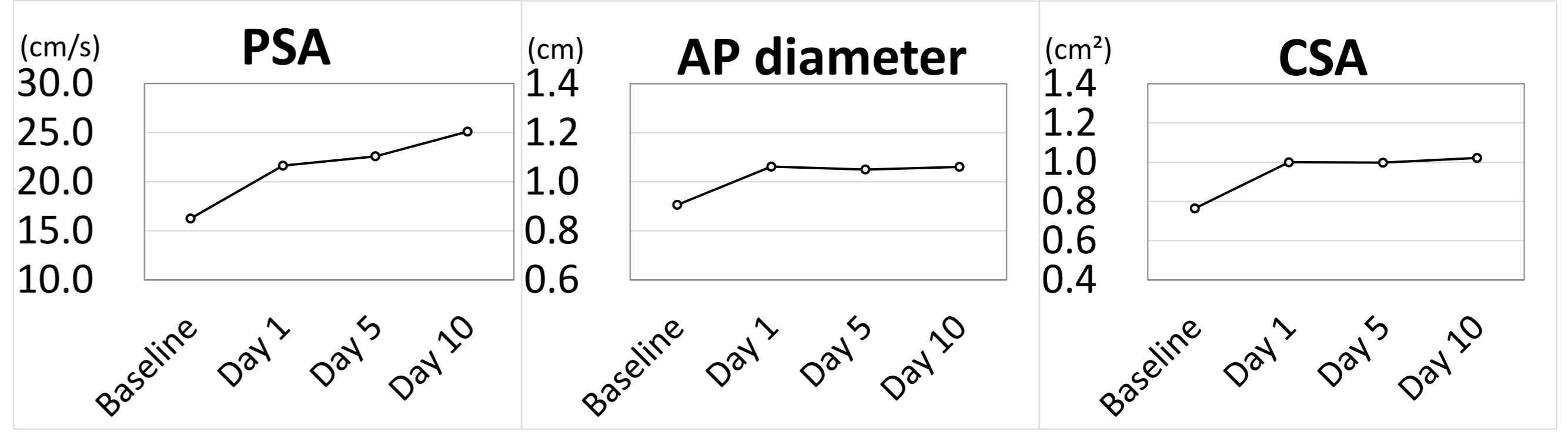


Figure 3. Changes in femoral vein hemodynamic parameters over 10 days of IPC.

Primary parameters (PSV, AP diameter, and CSA) increased significantly from baseline (all $p < 0.001$) and remained stable thereafter. This indicates an early and sustained improvement in venous flow without cumulative effects.

Secondary outcomes showed early reductions in limb volume, circumference, and edema indices, while pain showed progressive cumulative improvement, and BMI remained unchanged.

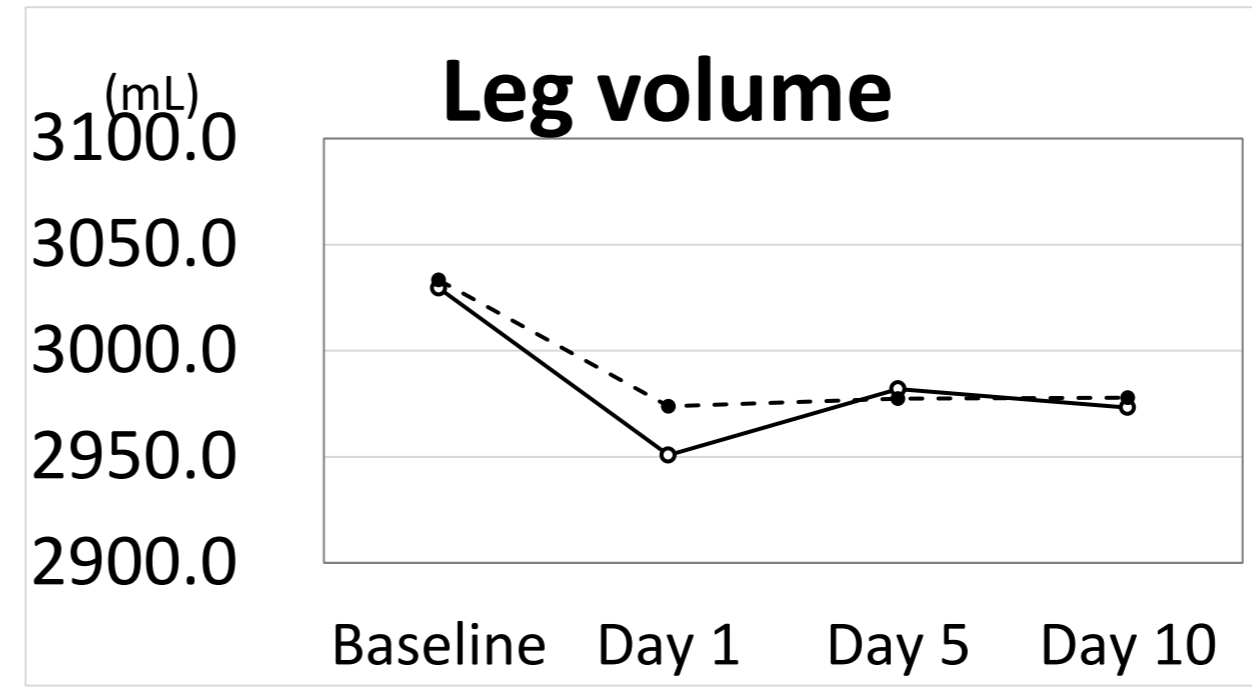


Figure 4. Changes in bilateral lower-limb volume by 3D scanning.

Limb volume decreased significantly at Day 1 and plateaued thereafter, indicating an early but non-cumulative reduction following IPC. Lt: solid line with open circles; Rt: dashed line with filled circles.

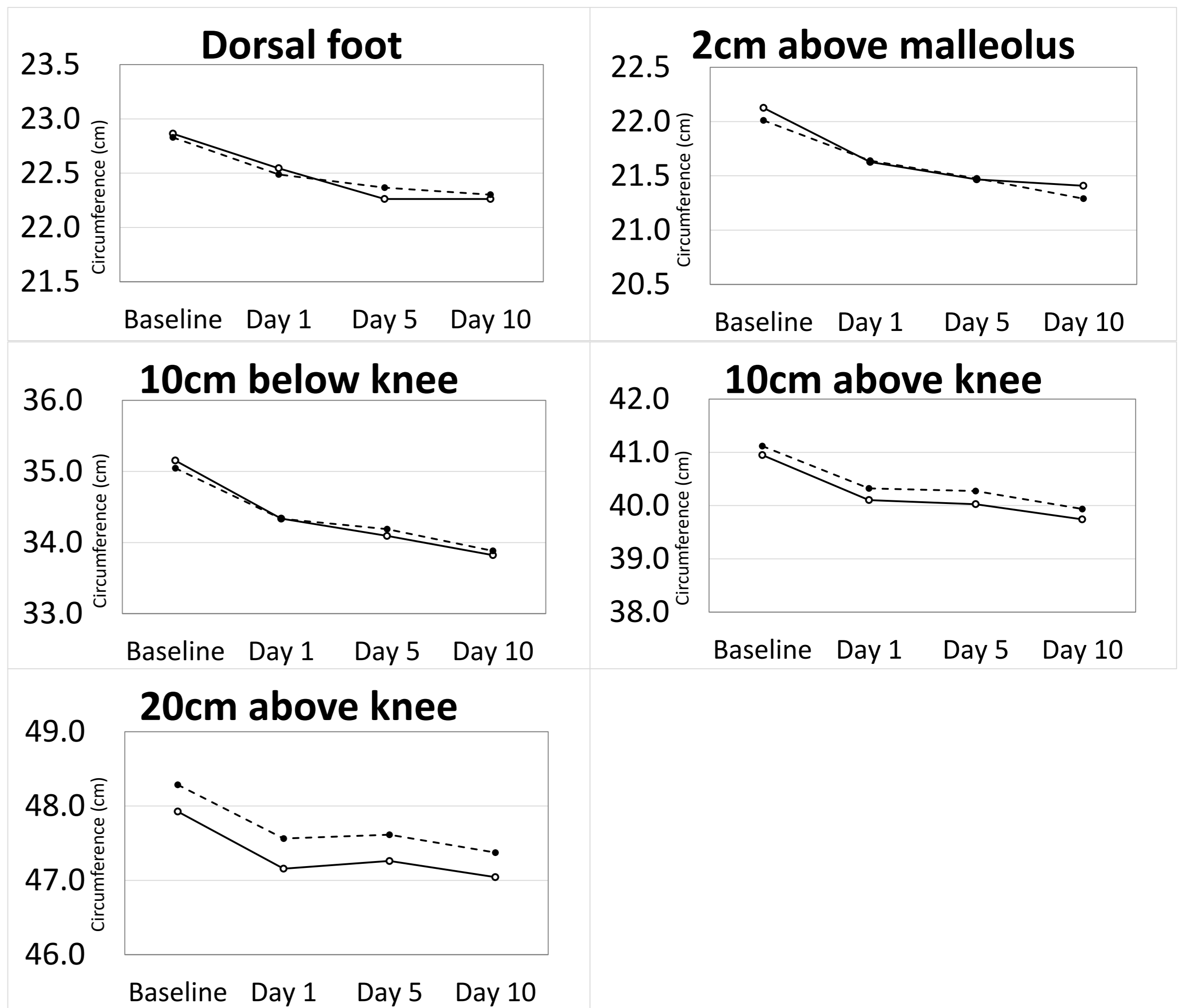


Figure 5. Changes in lower-limb circumference at five anatomical levels over 10 days of IPC.

Circumference decreased at all sites, with greater distal reduction, indicating edema improvement. Lt: solid line with open circles; Rt: dashed line with filled circles.

DISCUSSION

IPC improves venous flow and reduces edema and pain, with rapid effects that plateau early, suggesting a non-cumulative physiological response. Given the single-arm design and lack of a control group, causal inference is limited.

CONCLUSION

Sequential IPC was associated with improved venous hemodynamics and reduced limb edema and pain, with early and sustained effects.