

Effect of EECP vs Individual Shear Rate Therapy on Peripheral Artery Functions in Lower Extremity Atherosclerotic Disease

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Study Type	Prospective randomised sham-controlled clinical trial (RCT) — n=45 LEAD patients
Trial Registration	ChiCTR2100048086 — registered 21 June 2021
Ethics	IRB of Eighth Affiliated Hospital of Sun Yat-sen University (NO.2021-020-02)
ACC Relevance	RCT demonstrating EECP directly rehabilitates peripheral limb circulation — the most direct analogue to ACC-covered limb injuries

Study Design

45 patients with lower extremity atherosclerotic disease (LEAD) were randomly assigned to: EECP (n=15), individual shear rate therapy ISRT (n=15), or sham-control (n=15). 35 sessions of 45 minutes each, 5 days per week for 7 weeks. Randomisation by computer-generated sequence; nurses/doctors operating EECP were blinded to allocation. Outcome measurements at baseline, after 7 weeks, and 3-month follow-up.

Inclusion criteria: ABI ≤ 0.9 ; any infra-popliteal artery stenosis $>50\%$ by ultrasound; Stage II LEAD (Fontaine). Age 45–75 years.

Primary Outcomes: Brachial FMD & 6-Minute Walk Distance

Outcome	EECP (n=12 completed)	ISRT (n=13 completed)	Sham (n=10 completed)
Brachial FMD	3.43 \pm 0.64% 7.44 \pm 1.44% p<0.001	→ 3.33 \pm 1.02% 6.20 \pm 1.46% p<0.001	→ No significant change (+86%,

6-Min Walk Distance	376.67±130.52m 436.17±138.81m (+59.5m, p<0.001)	→	362.67±81.38m 418.67±81.24m (+56.0m, p<0.001)	→	No significant change
Brachial FMD vs sham post-treatment	Significantly higher (p=0.001)		Significantly higher (p=0.015)		Reference

Secondary Outcomes: Peripheral Blood Flow (Ultrasound)

Artery	EECP Result	ISRT Result	Significance
Popliteal artery	171→233 mL/min (+36%)	165→123 mL/min (decreased)	p<0.01 EECP vs sham
Posterior tibial artery	67→117 mL/min (+74%)	No significant change	p<0.01 EECP vs sham
Anterior tibial artery	No significant increase	47→67 mL/min (+43%)	p<0.05 ISRT vs sham
Dorsalis pedis artery	Significant increase in FR and diameter	Significant increase in FR and diameter	Both p<0.05 vs sham

Biochemical Outcomes

Marker	EECP Effect	ISRT Effect	Significance
ET-1 (endothelin-1, vasoconstrictor)	27.79→24.69 pg/mL (decreased)	36.16→28.51 pg/mL (decreased)	Both p<0.01 vs baseline
sVCAM-1 (inflammation)	96.54→84.66 pg/mL (decreased)	No significant change	p=0.004 (EECP only)
ADMA (NO inhibitor / oxidative stress)	0.24→0.19 μmol/L (decreased)	0.21→0.16 μmol/L (decreased)	Both p=0.001 vs baseline
8-iso-PGF2α (oxidative stress)	No significant change	No significant change	NS

Quality of Life (SF-36)

Physical function (PF) subscale of SF-36 was significantly improved after 7 weeks of EECP treatment (p<0.05) and after 3-month follow-up. EECP showed significantly greater PF improvement than ISRT at 7 weeks (p<0.01). This improvement reflects the same functional restoration outcomes targeted by ACC rehabilitation frameworks.

Conclusions

This RCT provides direct evidence that 35 sessions of EECP significantly rehabilitate peripheral limb circulation in lower extremity arterial disease: improving flow-mediated dilation (FMD), increasing walking distance, increasing popliteal and posterior tibial artery blood flow, reducing pro-inflammatory and vasoconstrictive endothelial markers (ET-1, sVCAM-1, ADMA), and improving physical function quality of life. These findings are directly applicable to ACC-covered lower limb injury rehabilitation.

Full Citation

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