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Custom Made Three Dimensional Printed Models for Pre-operative Planning and Simulation of Endovascular Treatment of Peripheral Artery Disease (3DPAD-1): A Single Blind Randomised Controlled Trial

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<RRH>3D Printed Models for Planning and Simulation in Endovascular Treatment of Peripheral Arteries

<AT>Custom Made Three Dimensional Printed Models for Pre-operative Planning and Simulation of Endovascular Treatment of Peripheral Artery Disease (3DPAD-1): A Single Blind Randomised Controlled Trial

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<H1>WHAT THIS PAPER ADDS

<p>This randomised controlled trial shows that custom made, in house made three dimensional (3D) printed vascular models used for pre-operative planning – rather than operator training – improve procedural efficiency during endovascular treatment of peripheral artery disease. Unlike conventional simulation platforms aimed at skill acquisition, this approach targets real case planning in experienced operators and is associated with fewer intra-operative events, shorter procedure duration, and reduced fluoroscopy time. The study clarifies where 3D printing adds value beyond training, supporting its selective use in complex endovascular interventions while also defining practical constraints for real world implementation.

<BEGIN ABSTRACT>

Objective: This trial aimed to assess whether custom made three dimensional (3D) printed vascular models improve procedural outcomes when used for pre-operative planning and simulation in endovascular treatment (EVT) of aorto-iliac-femoropopliteal peripheral artery disease (PAD).

Methods: This single centre, single blind randomised controlled trial (3DPAD-1), registered on ClinicalTrials.gov (Identifier: NCT07000097), enrolled consecutive patients scheduled for EVT between January 2022 and September 2024. Participants were randomised 1 : 1 to standard planning based on computed tomography angiography (CTA) alone (standard group, SG) or CTA plus 3D printed model based planning and simulation (3D model group, 3DMG). The prespecified coprimary endpoints were the cumulative 30 day incidence of peri-operative complications and total procedure duration. Secondary endpoints included technical success, contrast medium volume, radiation exposure, fluoroscopy time, and number of devices used.

Results: Of 166 patients screened, 106 were randomised (53 per arm); 99 underwent the allocated intervention (48 in the 3DMG, 51 in the SG). The cumulative incidence of complications was significantly lower in the 3DMG (20.8%) than in the SG (49.0%; $p = .006$). The univariable logistic model (OR 0.27, 95% CI 0.11 – 0.66; $p = .004$), the multivariable model (adjusted OR 0.22, 95% CI 0.08 – 0.60; $p = .004$), and the propensity weighted analyses (Average Treatment Effect OR 0.33, 95% CI 0.13 – 0.86; $p = .023$; Average Treatment Effect in the Overlap Population OR 0.35, 95% CI 0.14 – 0.79; $p = .023$) consistently confirmed the protective effect of the 3D model. Procedure duration was significantly shorter in the 3DMG (mean difference −40.3 minutes; $p < .001$), confirmed in adjusted and weighted models. No significant between group differences were observed in other peri-operative outcomes.

Conclusion: Custom made 3D printed models significantly reduced peri-operative complications and procedure duration in EVT for PAD, supporting their role in improving procedural planning and efficiency. These findings support the selective adoption of 3D printed models for complex endovascular interventions to enhance procedural efficiency and patient safety.

<END ABSTRACT>

<KW>Keywords: Custom made medical device, Endovascular surgery, Medical device, Patient care planning, Surgical simulation, Three dimensional printing, Vascular surgery

<H1>INTRODUCTION

<p>Endovascular surgery demands a high degree of precision and technical skills.[1–3] Advances in vascular technology highlight the need to enhance accuracy and safety,[4,5] making simulation and meticulous pre-operative planning key to improving performance and reducing intra-operative errors.[3,6–8]

According to current European Society for Vascular and Endovascular Surgery guidelines, simulation based training plays a pivotal role in the acquisition, refinement, and maintenance of technical skills.[6] Nevertheless, patient specific simulation remains uncommon in daily practice. Most virtual reality systems are designed for training rather than planning and even when adapted for patient specific use, these simulations are hindered by substantial time, expertise, and cost requirements, and by limited biomechanical fidelity[3]. Their high costs often limit accessibility and integration into routine training programmes.[9–11]

Standard planning for endovascular treatment (EVT) of peripheral artery disease (PAD) still presents important limitations.[12–14] Conventional two dimensional imaging fails to provide true three dimensional spatial understanding, haptic feedback, or the opportunity to rehearse procedures, and does not allow direct pathology visualisation.[4,9,15]

Three dimensional (3D) printing may offer a promising tool to overcome these shortcomings, enabling patient specific planning and rehearsal of interventions.[16–21] Additive manufacturing may provide an opportunity for detailed visualisation and hands on simulation of endovascular procedures before entering the operating room.[22–24]

A single centre randomised controlled trial (RCT) (3DPAD-1 study: Use of Three-Dimensional Printed Models for Endovascular Planning and Follow-up in Patients Affected by Aorto-Iliac-Femoro-Popliteal Arterial Disease Undergoing Balloon Angioplasty) was conducted to assess whether custom made 3D printed models for pre-operative planning and simulation improve procedural outcomes in EVT for PAD. The hypothesis was tested that their use reduces peri-operative complications and increases technical success compared with standard planning**.**

<H1>Methods

<H2>Design

<p>This was a single centre, single blind, RCT conducted at the authors' institution between January 2022 and September 2025 (final patient enrolled in September 2024). Eligible patients were those with an available pre-operative CT angiography (CTA) and an indication for EVT of aorto-iliac-femoropopliteal PAD, as determined during the study unit's weekly case review meeting. Patients were enrolled consecutively and randomised 1 : 1 into two groups: (1) 3D model group (3DMG), where a custom made 3D printed medical device was obtained for pre-operative planning and simulation; (2) standard group (SG), where pre-operative planning was conducted in a standard

fashion (using CTA alone). Patients were blinded to study group allocation, while vascular surgeons were not. The final treatment strategy was defined during a team meeting involving the operating surgeon and the full team, in line with the authors' routine clinical practice.

Patients were followed according to standard surveillance protocol after EVT; for the purpose of this study, clinical examination and the duplex ultrasound (DUS) were considered at 30 days.

The study protocol was developed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines[25] (Supplementary Table S1) and was registered on ClinicalTrials.gov (Identifier:NCT07000097). The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the North Emilia Broad Area (CE AVEN; protocol 15401, approval date 13 April 2021).

<H2>Inclusion, exclusion criteria

<p>Patients aged 18 to 89 years were eligible. Predefined inclusion criteria were severe intermittent claudication or chronic limb threatening ischemia (Rutherford clinical categories 3 – 5), scheduled EVT of aorto-iliac or femoropopliteal lesions, and written informed consent prior to study participation. Hybrid procedures (e.g., femoral endarterectomy with iliac EVT) were allowed; only the endovascular phase was analysed.

Crural interventions were excluded due to CTA limitations in evaluating tibial atherosclerosis and difficulties in reproducing small vessels with 3D printing.

A diagnostic CTA performed prior to enrolment was required. Exclusion criteria included declining to participate and the need for urgent treatment within 24 hours (insufficient time for 3D model printing).

<H2>*Data collection*

<p>Preprocedural data included demographic and clinical characteristics, cardiovascular risk factors, and lesion anatomy (location, length, calcifications, degree of stenosis). Additional information included intra-operative technical aspects, procedural outcomes, intra-operative and postoperative complications, and length of stay. Follow up data included DUS findings, particularly regarding restenosis, and clinical outcomes such as symptom improvement (improvement of at least one Rutherford category), limb salvage and survival. Intra-operative data were recorded by non-blinded operating surgeons, while postoperative and follow up data were collected during routine clinical care and were not necessarily assessed by blinded personnel.

All data were prospectively collected and recorded into a dedicated electronic case report form, within the Research Electronic Data Capture (REDCap, www.project-redcap.org) platform, hosted at the authors' institution.

<H2>Outcome and endpoints

<p>The aim of the trial was to evaluate the effectiveness of custom made 3D printed vascular models as an adjunct to pre-operative planning for EVT of aorto-iliac and femoropopliteal PAD. The study focused on short term (30 day) clinical and procedural outcomes following EVT.

The two prespecified coprimary endpoints were: (1) cumulative incidence of peri-operative complications within 30 days from the index EVT, a composite endpoint including any of the following events: more than one attempt to obtain vascular access at the planned site, technical failure of target lesion revascularisation, unplanned intra-operative procedures such as additional angioplasty or stenting, intra-operative vessel dissection or thrombosis, pseudoaneurysm, need for surgical or endovascular re-intervention within 30 days, and (2) total procedure duration, measured from puncture to sheath removal.

Secondary endpoints included technical success (completion of the intended endovascular procedure without conversion to open surgery and with residual stenosis < 30%); procedural and radiological parameters (contrast medium volume, radiation exposure, fluoroscopy time), and total number of devices used (guidewires, catheters, balloons, stents, introducers); and 30 day outcomes (postoperative complications related to the procedure, re-interventions, restenosis on DUS, limb salvage, mortality).

<H2>*Pre-operative imaging and 3D model manufacture*

<p>All patients underwent lower limb CTA using a 128 slice scanner following a standardised acquisition protocol as previously detailed.[9] In the 3DMG, arterial phase Digital Imaging and Communications in Medicine (DICOM) images were further processed with OsiriX MD 14.0 (Pixmeo SARL, Geneva, Switzerland),[9] and each patient underwent case by case model generation. The models were fabricated in house following a validated protocol previously described by the authors' group.[9] Dimensional fidelity was evaluated by comparing centreline reconstructions between the printed models and the original CTA data, demonstrating a strong correlation with patients' anatomy. Structured questionnaires confirmed the perceived realism and utility for planning and simulation. The total production time for a model was approximately 21.5 hours, including a printing phase of 11.5 hours and approximately 2 hours of postprocessing. Costs ranged between €140 and €165 per patient. Full technical details are available in the cited validation study.[9]

These models are classified as Class I custom made medical devices under the EU Medical Devices Regulation (EU MDR 2017/745), based on a written prescription from a qualified healthcare professional. DICOM images were converted into .STL files, refined using Meshmixer (San Francisco, CA, USA) and printed using stereolithography technology on a Form 2 printer (Formlabs, Somerville, MA, USA) with photoresponsive, medical grade resins.

Material selection was based on the medical prescription and the extent of calcifications, as previously reported.[9] This approach allowed reproduction of relevant lesion characteristics, including lumen geometry and vessel rigidity.

<H2>*Setting*

<p>Operative strategies were planned and rehearsed in the Clinical Simulation Laboratory within the authors' hospital, using real endovascular devices. Materials were re-used whenever possible, including the use of expired devices, to limit costs. Simulations were performed by the first operator, assisted by residents, typically the day before intervention, with duration at the operator's discretion (usually 30 – 60 minutes). A simulation setup was developed to replicate the angiographic suite environment using a light panel and a camera connected to a monitor, without the need for actual fluoroscopy, as previously described (Fig. 1).[9]

All EVT were performed by three vascular surgeons with very similar experience in PAD interventions (14 – 16 years), either in a dedicated operating theatre with a mobile C-arm (Ziehm Vision RFD Hybrid Edition, Ziehm Imaging GmbH, Nuernberg, Germany) or in an angiographic suite (Allura Xper FD20 system, Philips, Amsterdam, The Netherlands).

<H2>*Randomisation and allocation concealment*

<p>Randomisation was performed using a computer generated sequence created by an independent statistician, ensuring allocation concealment. No blocking or stratification was applied. Allocation was managed via a password protected REDCap module accessible only to the statistician, which automatically assigned participants at enrolment.

<H2>*Sample size and power calculation*

<p>Based on the number of eligible patients treated annually in the authors' centre, it was estimated that 100 participants (50 per arm) could be enrolled during the recruitment period. A sample of 100 subjects provides 83% power to detect an absolute 30% difference in peri-operative complication rates between groups, using a two sided Fisher's exact test with $\alpha = .05$. With the same sample size, it 86% power was also estimated to detect a 20 minute difference in mean procedure duration (relative reduction 22%), using a two sided *t* test at the same significance level.

<H2>*Statistical analysis*

<p>Descriptive statistics for continuous variables included mean with standard deviation (SD), and median with interquartile range (IQR), as appropriate. Normality was assessed using graphical methods (histograms and Q–Q plots) and the Shapiro–Wilk test. Categorical variables were summarised as absolute and relative frequencies (%).

For the second coprimary endpoint (operative time), the prespecified primary analysis consisted of a comparison of means between groups using an independent samples *t* test. Given

potential skewness, median and IQR were additionally reported and the distribution visualised using violin plots. Univariable and multivariable logistic and linear regressions were performed for interpretative purposes.

Sensitivity analyses were conducted for the first coprimary endpoint. To account for residual baseline imbalance, a propensity score weighted analysis was performed.

Secondary endpoints were analysed using the chi square test or Fisher's exact test for categorical variables, and the independent samples *t* test or Mann–Whitney test for continuous variables. Two sided *p* values < .050 were considered significant. Because there were two coprimary endpoints, a Bonferroni correction was applied, allocating $\alpha = .05$ (two sided) to each.

An additional exploratory analysis used a propensity score including key covariates (age, sex, number of lesions, and Rutherford class 5). Stabilised inverse probability of treatment weights (IPTW, 1 – 99% truncation) were applied to estimate the marginal average treatment effect (ATE) and overlap weights to estimate the average treatment effect in the overlap population (ATO). Weighted logistic regression was used for peri-operative complications and weighted linear regression for procedure duration, with robust standard errors. These weighting approaches retained the full study cohort and did not exclude patients, assigning different statistical weights to individual observations.

All efficacy analyses were conducted according to a modified intention to treat (mITT) principle. The analytical population included all randomised patients who underwent the allocated intervention, consistent with the procedural nature of the trial. No per protocol analyses were performed and no imputation for missing data was undertaken.

Statistical analyses were performed using STATA 18.0 (StataCorp LLC, College Station, TX, USA) and R 4.5.1 (cran.r-project.org).

<H1>**RESULTS**

<p>A total of 166 patients was assessed for eligibility, of which 106 were consecutively enrolled and randomised. In the 3DMG, five patients did not receive the allocated intervention due to death prior to the procedure (*n* = 1), change in clinical condition (*n* = 3), or a cardiac complication (*n* = 1); in the SG, two patients withdrew consent to the intervention (Fig. 2).

<H2>Baseline characteristics

<p>The two analysed groups were comparable in terms of demographic characteristics, cardiovascular risk factors, comorbidities, and lesion characteristics (Table 1). The only significant between group differences concerned pre-operative medical therapy: single antiplatelet therapy was more frequent in the 3DMG (42/48, 79.2% *vs.* 29/51, 54.7%; *p* = .007), whereas dual antiplatelet

therapy was more common in the SG (17/51, 32.1% *vs.* 4/48, 7.5%; $p = .002$). Procedures were evenly distributed among the three operators in both groups ($p = .98$).

<H2>Intra-operative data

<p>Technical success was significantly higher in the 3DMG (47/48, 97.9%) than in the SG (42/51, 82.4%; $p = .010$). The median procedure duration was significantly shorter in the 3DMG (55.5 [IQR 35.0, 81.0] *vs.* 82.0 [60.0, 120.0] minutes; $p = .001$). Intra-operative mortality occurred in 1/51 SG patients (2.0%) and in none of the 3DMG ($p = .33$).

In the 3DMG, a lower rate of patients was recorded with multiple (> 1) intra-operative complications ($p = .003$). Among specific complications, arterial dissection ($p = .006$), and bailout stenting ($p = .034$) were significantly less frequent in the 3DMG. The 3DMG also required less contrast medium (median 66.5 [IQR 33.0, 100.0] *vs.* 72.0 [59.0, 130.0] mL; $p = .027$) and had shorter fluoroscopy time (15.0 [7.5, 24.0] *vs.* 23.7 [14.7, 36.3] minutes; $p = .003$).

No significant between group differences were observed regarding the number of arterial punctures, guidewires, catheters, or use of closure devices, while small numerical differences were noted in balloon and stent use (Table 2).

<H2>Primary endpoints

<p>Regarding the two prespecified coprimary endpoints, for the first (cumulative incidence of peri-operative complication rate), 10/48 (20.8%) patients in 3DMG and 25/51 (49.0%) in SG had at least one complication ($p = .006$). Figure 3 shows the component breakdown of this composite endpoint. The distribution and rates per arm across intra-operative events, immediate success/failure, postoperative events, 30 day follow up, and the cumulative primary endpoint are presented in Supplementary Figure S1.

The univariable model (OR 0.27, 95% CI 0.11 – 0.66; $p = .004$) and the multivariable logistic model confirmed the protective effect of 3DMG (adjusted OR 0.22, 95% CI 0.08 – 0.60; $p = .004$) (Table 3).

When lesions were dichotomised by median length (cutoff 7 cm), the reduction in peri-operative complications associated with 3D model based planning was numerically more pronounced in longer lesions (22.7% [5/22] *vs.* 63.0% [17/27]) than in shorter lesions (19.2% [5/26] *vs.* 33.3% [8/24]). Regarding plaque morphology, similar event proportions were recorded for calcified lesions (33.3% [6/18] *vs.* 31.8% [7/22]) (Supplementary Table S2).

Concerning the second coprimary endpoint (procedural duration in minutes), the mean time in 3DMG was significantly lower (means 60.3 *vs.* 100.6, $p < .001$) (Supplementary Fig. S2). The univariable model (β −40.3 minutes, standard error [SE] 10.4; $p < .001$) and the multivariable linear

model confirmed the shorter duration of 3DMG (adjusted β = −33 minutes, SE 10.9; *p* = .002) (Table 3).

<H3>IPTW sensitivity analysis. <p>As baseline descriptive comparisons may suggest slight chance imbalances, a prespecified sensitivity analysis using the propensity score was performed. Covariate balance improved substantially after weighting (Supplementary Figure S3). Effect direction remained consistent with the main analysis, although the magnitude of the effect was slightly attenuated. On the ATE scale, allocation to the 3DMG was associated with fewer peri-operative complications (OR 0.33, 95% CI 0.13 – 0.86; *p* = .023) and a shorter procedure duration (−31.3 minutes, 95% CI −51.8 – −10.9; *p* = .003). Similar results were obtained using overlap weights (ATO; Table 3).

<H2>*Short term clinical and procedural results*

<p>At the 1 month follow up, outcomes were comparable between the two groups (Supplementary Table S3). In the SG, one patient was lost to follow up and three deaths (6%) occurred: one due to cardiovascular causes, one due to stroke, and one related to chronic renal failure. Re-intervention was required in 5/50 patients (10%) in the SG and in 1/48 patients (2.1%) in the 3DMG (*p* = .205). The re-intervention in the 3DMG consisted of a femoropopliteal bypass; in the SG, two major amputations, two endovascular procedures, and one femorofemoral crossover bypass.

<H1>DISCUSSION

This RCT suggests that 3D printed models improve EVT outcomes. The first coprimary endpoint was intentionally defined as a composite of intra-operative technical events and clinically meaningful 30 day complications, to capture overall procedural burden. The reduction (20.8% *vs.* 49.0%) in the composite endpoint was mainly driven by fewer intra-operative complications and technical failures, whereas 30 day clinically relevant complications were less frequent and comparable between groups. This pattern is consistent with the hypothesised mechanism of 3D printed models, which primarily influence procedural planning and execution rather than postprocedural progression. Accordingly, the observed benefit appears to be mainly related to intra-operative performance rather than to short term clinical outcomes.

The use of 3D printed models was associated with shorter procedure duration (mean difference −40.3 minutes) and reduced contrast medium requirement, rather than a clear reduction in material consumption. These advantages are clinically relevant, particularly in patients with impaired renal function or in complex anatomies. The exploratory descriptive analyses provided additional context to these findings: the observed patterns suggest that custom made 3D printed models may be most beneficial in selected complex EVT, particularly in longer lesions. In contrast, no apparent advantage was observed in heavily calcified lesions, possibly due to the intrinsic

difficulty of lesion crossing and the current limitations of 3D printing in reproducing severe calcifications. These findings should therefore be considered hypothesis generating and may help guide more selective use of 3D printed models in clinical practice.

The economic feasibility of in house printing using stereolithography technology has already been proved, with costs ranging between €140 and €165 per patient.[9] This approach produces high fidelity 3D printed models with strong dimensional agreement to patient anatomy, and is cheaper than outsourcing.[9] Implementation requires dedicated equipment, trained personnel, and sufficient time for model production, which may represent a barrier in centres with limited resources. However, once established, in house production becomes reproducible and progressively more efficient.

In Europe 3D printed models are subject to the EU Medical Device Regulation (EU MDR 2017/745). The present custom made 3D printed models are non-invasive Class I devices, the lowest risk category. Regulatory frameworks may differ across healthcare systems and must be considered when implementing this technology.

The results of the present study suggest that extending the use of 3D printed models selectively to complex cases could represent a valuable compromise between clinical efficacy and resource utilisation. Additionally, retaining printed models for resident education enhances their utility, spreading the cost over both patient care and surgical training.

Future developments may further expand the role of 3D printing in vascular surgery. Multimaterial printing could allow more realistic vessel wall reproduction, albeit with higher costs.[21] Integration with augmented reality may allow immersive procedural rehearsal.[11,26,27] 3D printing could also contribute to personalised medicine.[28–30]

The first limitation of 3D printing is that it requires time, making it unsuitable for urgent cases. Secondly, in this study, only two types of resins were tested, which may have limited haptic feedback. Thirdly, the technique was applied only to the aorto-iliac and femoropopliteal segments, due to imaging and printing constraints. Fourthly, as a single blind trial, operators and outcome assessment were not blinded to group allocation, which may have introduced observer bias. Finally, the materials used during simulations were re-used to reduce costs, which may have reduced the fidelity of haptic feedback. Costs themselves may also represent a limitation, as the availability of in house 3D printing facilities is not universal and expenses may be prohibitive for some centres.

<H2>Conclusions

Custom made 3D printed models for pre-operative planning and simulation of aorto-iliac and femoropopliteal EVT in PAD are feasible and appear to be associated with improved procedural

outcomes. Their selective use in complex anatomies or in patients where shorter operative times and reduced contrast exposure are desirable may provide clinical benefits.

<H1>CONFLICT OF INTEREST

None.

<H1>FUNDING

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<H1>APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/XXXXX.

<H1>REFERENCES

<REF>

1 Sulzer T, Tenorio ER, Mesnard T, Vacirca A, Baghbani-Oskouei A, De Bruin JL, et al. Intraoperative complications during standard and complex endovascular aortic repair. *Semin Vasc Surg* 2023;**36**:189–201.

2 Banerjee S, Jeon-Slaughter H, Tsai S, Mohammad A, Foteh M, Abu-Fadel M, et al. Comparative assessment of procedure cost and outcomes between guidewire and crossing device strategies to cross peripheral artery chronic total occlusions. *JACC Cardiovasc Interv* 2016;**9**:2243–52.

3 Desender L, Van Herzeele I, Lachat M, Duchateau J, Bicknell C, Teijink J, et al. A multicentre trial of patient specific rehearsal prior to EVAR: impact on procedural planning and team performance. *Eur J Vasc Endovasc Surg* 2017;**53**:354–61.

4 Bradbury AW, Hall JA, Popplewell MA, Meecham L, Bate GR, Kelly L, et al. Plain versus drug balloon and stenting in severe ischaemia of the leg (BASIL-3): open label, three arm, randomised, multicentre, phase 3 trial. *BMJ* 2025:e080881.

5 Farber A, Menard MT, Conte MS, Kaufman JA, Powell RJ, Choudhry NK, et al. Surgery or endovascular therapy for chronic limb-threatening ischemia. *N Engl J Med* 2022;**38**:2305–16.

6 Wanhainen A, Van Herzeele I, Bastos Goncalves F, Bellmunt Montoya S, Berard X, Boyle JR, et al. Editor's Choice -- European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms. *Eur J Vasc Endovasc Surg* 2024;**67**:192–331.

7 Ucci A, Perini P, Freyrie A, Schreve MA, Ünlü Ç, Huizing E, et al. Endovascular and Surgical venous arterialization for no-option patients with chronic limb-threatening ischemia: a systematic review and meta-analysis. *J Endovasc Ther* 2025;**32**:1301–16.

8 Saadi S, Nayfeh T, Rajjoub R, Hasan B, Firwana M, Jawaid T, et al. A systematic review supporting the Society for Vascular Surgery guideline update on the management of intermittent claudication. *J Vasc Surg* 2025;**82**:688–97.

9 Mersanne A, Foresti R, Martini C, Caffarra Malvezzi C, Rossi G, Fornasari A, et al. In-house fabrication and validation of 3D-printed custom-made medical devices for planning and simulation of peripheral endovascular therapies. *Diagnostics* 2024;**15**:8.

10 Foresti R, Fornasari A, Bianchini Massoni C, Mersanne A, Martini C, Cabrini E, et al. Surgical medical education via 3D bioprinting: modular system for endovascular training. *Bioengineering* 2024;**11**:197.

11 Rudarakanchana N, Van Herzeele I, Desender L, Cheshire NJW. Virtual reality simulation for the optimization of endovascular procedures: current perspectives. *Vasc Health Risk Manag* 2015;**11**:195–202.

12 Song P, Rudan D, Zhu Y, Fowkes FJI, Rahimi K, Fowkes FGR, et al. Global, regional, and national prevalence and risk factors for peripheral artery disease in 2015: an updated systematic review and analysis. *Lancet Glob Health* 2019;**7**:e1020–30.

13 Nordanstig J, Behrendt C-A, Baumgartner I, Belch J, Bäck M, Fitridge R, et al. Editor's Choice -- European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Asymptomatic Lower Limb Peripheral Arterial Disease and Intermittent Claudication. *Eur J Vasc Endovasc Surg* 2024;**67**:9–96.

14 Conte MS, Bradbury AW, Kolh P, White JV, Dick F, Fitridge R, et al. Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia. *Eur J Vasc Endovasc Surg* 2019;**58**:S1–S109.e33.

15 Stana J, Grab M, Kargl R, Tsilimparis N. 3D printing in the planning and teaching of endovascular procedures. *Radiologie* 2022;**62**(S1):28–33.

16 Branzan D, Geisler A, Grunert R, Steiner S, Bausback Y, Gockel I, et al. The influence of 3D printed aortic models on the evolution of physician modified stent grafts for the urgent treatment of thoraco-abdominal and pararenal aortic pathologies. *Eur J Vasc Endovasc Surg* 2021;**61**:407–12.

17 Colacchio EC, Berton M, Volpe A, Guariento A, Dall'Antonia A, Antonello M. Three-dimensional printing application in a challenging case of type II endoleak. *J Endovasc Ther* 2024;**31**:474–8.

18 Oliny A, Fabre D, Fontaine V, Decante B, Haulon S. Pre-clinical evaluation of a new generation bridging stent for fenestrated endovascular aneurysm repair using realistic 3D printed aneurysm models. *Eur J Vasc Endovasc Surg* 2025;**69**:910–8.

19 Zhao Z, Han Y, Pan C, Hu J, Keyoumu R, Li T, et al. Three-dimensional printing assisted physician-modified fenestrated endografts for thoracic endovascular aortic aneurysm repair in Zone 1. *J Vis Exp* 2025;(218):67893.

20 Coles-Black J, Bolton D, Robinson D, Chuen J. Utility of 3D printed abdominal aortic aneurysm phantoms: a systematic review. *ANZ J Surg* 2021;**91**:1673–81.

21 Catasta A, Martini C, Mersanne A, Foresti R, Bianchini Massoni C, Freyrie A, et al. Systematic review on the use of 3D-printed models for planning, training and simulation in vascular surgery. *Diagnostics* 2024;**14**:1658.

22 Mafeld S, Nesbitt C, McCaslin J, Bagnall A, Davey P, Bose P, et al. Three-dimensional (3D) printed endovascular simulation models: a feasibility study. *Ann Transl Med* 2017;**5**:42.

23 Leng S, McGee K, Morris J, Alexander A, Kuhlmann J, Vrieze T, et al. Anatomic modeling using 3D printing: quality assurance and optimization. *3D Print Med* 2017;**3**:6.

24 Wippel D, Ouaret M, Gizewski ER, Kluckner M, Enzmann FK, Wipper S. Simulation based training for iliac endovascular interventions: 3D printed versus digital models. *Eur J Vasc Endovasc Surg* 2025;**70**:403–4.

25 Hopewell S, Chan A-W, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 statement: Updated guideline for reporting randomised trials. *PLoS Med* 2025;**22**:e1004587.

26 Eves J, Sudarsanam A, Shalhoub J, Amiras D. Augmented reality in vascular and endovascular surgery: scoping review. *JMIR Serious Games* 2022;**10**:e34501.

27 Faizan Siddiqui M, Jabeen S, Alwazzan A, Vacca S, Dalal L, Al-Haddad B, et al. Integration of Augmented reality, virtual reality, and extended reality in healthcare and medical education: a glimpse into the emerging horizon in LMICs—a systematic review. *J Med Educ Curric Dev* 2025;**12**:23821205251342315.

28 Ghezzi B, Foresti R, Scialoia LP, Botti M, Mersanne A, Ratto F, et al. Preliminary evaluation of 3D-printed alginate/gelatin scaffolds for protein fast release as suitable devices for personalized medicine. *Biomedicines* 2025;**13**:1365.

29 Foresti R, Rossi S, Pinelli S, Alinovi R, Sciancalepore C, Delmonte N, et al. In-vivo vascular application via ultra-fast bioprinting for future 5D personalised nanomedicine. *Sci Rep* 2020;**10**:3205.

30 Grottkau BE, Hui Z, Ran C, Pang Y. Fabricating vascularized, anatomically accurate bone grafts using 3D bioprinted sectional bone modules, in-situ angiogenesis, BMP-2 controlled release, and bioassembly. *Biofabrication* 2024;**16**:045008.

Figure 1. A Simulation setup scheme developed to replicate the angiographic suite environment: light panel, camera, 3D printed model, laptop, monitor. B Operator performing the simulation.

Figure 2. CONSORT flow diagram. A total of 166 patients with an available pre-operative computed tomography angiography and an indication for endovascular treatment of aorto-iliac-femoropopliteal peripheral artery disease was assessed for eligibility, of whom 106 were randomised into two groups: 53 to the standard group (SG) and 53 to the 3D model group (3DMG). Of these, 51 patients in the standard group and 48 patients in the 3D model group underwent the allocated intervention and were included in the primary outcome analysis. Secondary outcome analysis included 50 patients in the standard group and 48 patients in the 3D model group.

Figure 3. Component breakdown of the composite primary endpoint by treatment group, in patients requiring endovascular treatment of aorto-iliac-femoropopliteal peripheral artery disease. Participants were randomised to standard planning based on computed tomography angiography (CTA) alone (standard group, SG) or CTA plus 3D printed model based planning and simulation (3D model group, 3DMG). Bars represent the percentage of patients experiencing each component; numbers above bars indicate events/total patients. The overall reduction in the composite endpoint is mainly driven by fewer intra-operative complications and technical failures in the 3D model group, while postoperative and 30 day complications were less frequent in both groups. IC = intra-operative complications; TF = technical failure; PC = postoperative complications; 30dC = 30 days complications; PCCR, peri-operative cumulative complication rate.

Table 1. Baseline demographic, clinical, and lesion characteristics in 106 patients with aorto-iliac-femoropopliteal peripheral artery disease randomised to standard planning for endovascular treatment based on computed tomography angiography (CTA) alone (standard group, SG) or CTA plus 3D printed model based planning and simulation (3D model group, 3DMG).

Baseline characteristics	**SG** *n*=53	**3DMG** *n*=53

Age – y, median (range)	74 (57 – 88)	71 (48 – 87)
Male, sex	42 (79.2)	38 (71.7)
BMI – kg/m^2	26.0 (23.5, 28.9)	24.3 (23.4, 29.4)
Rutherford category		
Rutherford cat. 3 (Intermittent claudication)	18 (35.3)	22 (44.9)
Rutherford cat. 4 (Rest pain)	5 (9.8)	11 (22.4)
Rutherford cat. 5 (Tissue loss)	28 (54.9)	16 (32.7)
Cardiovascular risk factors		
Current smoking	18 (34.0)	19 (35.8)
Former smoking	23 (43.4)	20 (37.7)
Chronic obstructive pulmonary disease	13 (24.5)	13 (24.5)
Overweight (BMI >25)	18 (34.0)	14 (26.4)
Obesity (BMI >30)	9 (17.0)	10 (18.9)
Hypertension	45 (84.9)	41 (77.4)
Diabetes mellitus	25 (47.2)	28 (52.8)
Chronic kidney disease	11 (20.8)	6 (11.3)
Ischaemic heart disease	18 (34.0)	12 (22.6)
Atrial fibrillation	12 (22.6)	11 (20.8)
Heart failure	6 (11.3)	4 (7.5)
Dyslipidaemia	36 (67.9)	33 (62.3)
Pre-operative medical therapy		
Single antiplatelet therapy	29 (54.7)	42 (79.2)
Dual antiplatelet therapy	17 (32.1)	4 (7.5)
Vitamin K antagonists	4 (7.5)	4 (7.5)
Direct oral anticoagulants	11 (20.8)	10 (18.9)
Statins	34 (64.2)	25 (47.2)
Lesion characteristics		
Aorto-iliac lesion	32 (60.4)	36 (67.9)
Femoropopliteal lesion	21 (39.6)	17 (32.1)
Lesion length	8.0 (3.5, 15.0)	6.4 (3.5, 10.0)
Stenosis severity	90.0 (80.0, 95.0)	90.0 (80.0, 95.0)
Calcified plaque*	22 (41.5)	18 (33.9)

Data are presented as *n* (%) or median (interquartile range), unless stated otherwise. *p* value from Kruskal–Wallis test for continuous variables; *p* values from Pearson chi square test for categorical variables. BMI = body mass index.

[*]Circumferential calcifications covering > 80% of the vessel circumference over at least 5 cm in the vascular tract planned to undergo angioplasty.

Table 2. Procedural and intra-operative parameters in 99 patients with aorto-iliac-femoropopliteal peripheral artery disease randomised to standard planning for endovascular treatment based on computed tomography angiography (CTA) alone (standard group, SG) or CTA plus 3D printed model based planning and simulation (3D model group, 3DMG).

Intra-operative data	**SG** *n*=51	**3DMG** *n*=48	***p*** **value**
Procedure duration – min	82.0 (60.0, 120.0)	55.5 (35.0, 81.0)	.001
Technical success	42 (82.4)	47 (97.9)	.01
Intra-operative mortality	1 (2.0)	0 (0)	.33
Multiple (>1) intra-operative complications[*]	18 (35.3)	5 (10.4)	.003
Specific intra-operative complications[†]			
Arterial dissection	12 (23.5)	2 (4.2)	.006
Thrombosis	0 (0)	0 (0)	–
Unplanned additional procedures	8 (15.7)	2 (4.2)	.057
Embolization	1 (2.1)	1 (2.0)	.96
Bailout stenting	7 (13.7)	1 (2.1)	.034
Pseudoaneurysm	1 (2.0)	0 (0)	.33
Conversion to surgical access	1 (2.0)	0 (0)	.33
Hybrid procedures	17 (33.3)	14 (29.2)	.65
Contrast medium volume – mL	72.0 (59.0, 130.0)	66.5 (33.0, 100.0)	.027
Iomeron 300	40 (78.4)	34 (70.8)	.38
Visipaque 270/320	11 (21.6)	14 (29.2)	.38
Radiation exposure dose – cGy·cm²	8 564.8 (2 413.9, 19 164.1)	5 416.9 (2 172.9, 15 715.0)	.26
Fluoroscopy time – min	23.7 (14.7, 36.3)	15.0 (7.5, 24.0)	.003
Arterial punctures	1.0 (1.0, 1.0)	1.0 (1.0, 1.0)	.62
Guidewires	3.0 (2.0, 4.0)	2.0 (2.0, 3.0)	.13
Catheters	2.0 (1.0, 2.0)	1.0 (1.0, 2.0)	.26
Balloons	2.0 (1.0, 4.0)	2.0 (1.0, 2.0)	.015
Stents	1.0 (1.0, 2.0)	2.0 (1.0, 2.0)	.001
Percutaneous closure devices	9 (17.6)	11 (22.9)	.51

Data are presented as *n* (%) or median (interquartile range).

[*]Defined as patients experiencing more than one intra-operative complication.

[†]Event frequency for specific complications, reported per total number of patients per group.

Table 3. Univariable, multivariable, and weighted effect estimates for the two coprimary endpoints, cumulative 30 day incidence of peri-operative complications and total procedure duration, in patients with aorto-iliac-femoropopliteal peripheral artery disease randomised to standard planning for endovascular treatment based on computed tomography angiography (CTA) alone (standard group, SG) or CTA plus 3D printed model based planning and simulation (3D model group, 3DMG).

Model type	Intra-operative complications (OR, 95% CI; *p* value)	Procedure duration – min (β, 95% CI)
Univariable model	0.27, 0.11–0.66; .004	−40.29, −60.97 – −19.62; < .001
Multivariable model	0.22, 0.08–0.60; .004[*]	−33.01, −53.37 – −12.66; .002[†]
Weighted model (ATE)	0.33, 0.13–0.86; .023	−31.34, −51.76 – −10.91; .003
Weighted model (ATO)	0.35, 0.14–0.79; .025	−32.07; −52.48 – −11.61; .002

Estimates derived from logistic and linear regression models for the binary (intra-operative complications) and continuous (procedure duration) coprimary endpoints. OR = odds ratio; β = regression coefficient; CI = confidence interval; ATE = average treatment effect; ATO = average treatment effect in the overlap population.

[*] Variables included in the multivariable models according to a backward stepwise selection procedure were: number of lesions, smoking status, ischaemic heart disease, heart failure, and antiplatelet therapy.

[†] Variables included in the multivariable models according to a backward stepwise selection procedure were: number of lesions and heart failure.