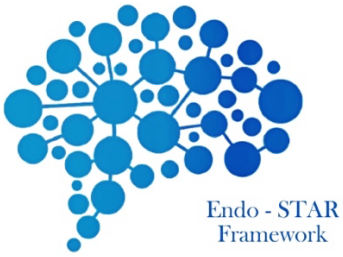

The Endo-STAR Framework* a practical guide to the framework and completion of the checklist

The Endo-STAR framework is a practical aid to help design, perform and report clinical trials of lower limb endovascular interventions for peripheral arterial disease. It can be used at different stages of the clinical trial and for different purposes:

- **Writing the trial protocol**
- **Standardising the intervention**
- **Monitoring adherence to the trial protocol**
- **Reporting trial results**

The Endo-STAR framework checklist is available in appendix 4, and the full version of the framework is available on the Endo-STAR framework website (www.endo-star.com). This document is a guide on how to use the framework in conjunction with the checklist.

General principles on how to use the framework and checklist:

-For the purpose of the intervention description, it is assumed that the intervention begins when the patient arrives in the operating room and ends when the patient leaves the operating room.

-It is not compulsory to describe, standardise, monitor and report all steps and components of the intervention. However, it is important for the research team to consider all of these individual components of the endovascular intervention "a priori" from the design stage of the trial and document the decision clearly in the trial protocol. Please note that the same considerations should be applicable to both the main intervention and the comparator intervention.

-The Endo-STAR framework Checklist should be used as a tool to check that these points have been considered by the research team and document the outcomes. The checklist can be downloaded as appendix 4 or from the Endo-STAR framework website and can be included as part of the protocol publication or an online appendix.

In an explanatory trial (such as a first in vivo trial), the research team might be willing to describe, standardize and report each step and component of the procedure.

In a pragmatic trial the research team might instead be keen to leave some components of the intervention (for example the type of access or the type of closure device) at the discretion of the operator while standardizing and monitoring other steps and components to ensure that the investigated procedure is performed in a similar way between all participants across all trial centres and can be replicated by others.

Zywicka EM, Moore AJ, Twine C, et al. Endovascular treatment of peripheral arterial disease: Endo-STAR framework for the design, conduct, and reporting of trials. *Br J Surg*. 2025;112(4):znaf020. doi:10.1093/bjs/znaf020

- If a trial is already ongoing similar consideration should be applicable at the reporting stage where the research team should consider reporting an as accurate as possible description of the investigated intervention.

- If the information is too long and complex to be described in the primary paper, alternative formats should be used (separate publication of trial protocol, appendix), and details of where this can be obtained should be provided in the primary paper.

SECTION	
1. EXPERTISE	**This section provides guidance on how to describe the expertise, training and support for the operator. The term "operator" refers to the person who delivers the intervention.** It is important to describe the expertise, including the specialist's background or clinical specialty (vascular surgeon, interventional radiologist, cardiologist, angiologist), pre-existing specific skills, experience, details of any training specific to the intervention and procedural competence / support. More than one operator is acceptable. However, defining the primary and secondary operator while describing their expertise is required. This can be used to describe the eligibility criteria for care providers at the design stage and to describe those who provided the intervention at the reporting stage.
2. SETTING	**This section provides guidance on how to describe the setting in which the intervention is being investigated.** The term "setting" describes the circumstances in which the intervention is performed. This can be variable based on the timing of the procedure (elective / urgent / emergency), the infrastructure (different types of hospitals or ambulatory centres) and, more specifically, the specific environment or location (operating room, hybrid theatre, interventional radiology / cardiology / angiology suite) and equipment (fixed or mobile imaging). This can be helpful to describe the eligibility criteria for centres at the design stage and to describe where the interventions were performed at the reporting stage.

Zywicka EM, Moore AJ, Twine C, et al. Endovascular treatment of peripheral arterial disease: Endo-STAR framework for the design, conduct, and reporting of trials. *Br J Surg*. 2025;112(4):znaf020. doi:10.1093/bjs/znaf020

3. ANAESTHESIA	**This section provides guidance on how to describe the anaesthesia being used while performing the intervention.** More than one type of anaesthesia is possible, as well as a combination of different modalities (for example, local anaesthesia and sedation or local anaesthesia and a popliteal nerve block in patients with severe rest pain).
4. IMAGING	
Pre-procedural imaging	The initial subsection "Pre-procedural imaging" refers to the imaging performed before the intervention to plan and decide revascularization options, characterize and classify the lesions. These includes, for example, preoperative CTA, MRA, and arterial Duplex scans. It should also be considered to establish a priori and clearly document based on which imaging modality or standard, the reference vessel diameter and/or length will be measured to select the most appropriate device. This is often done either based on pre-procedural imaging or baseline imaging.
Baseline imaging	The subsection "Baseline imaging" refers to the initial imaging performed at the beginning of the procedure to assess the anatomy and the lesions requiring intervention before performing any treatment. The most common imaging modality is a diagnostic angiogram, but other modalities can also be utilized, such as external and intravascular US or Optical Coherence Tomography. It should be considered performing the baseline imaging in a standardised mode, considering the appropriate modality for the visualization and evaluation of all relevant anatomical segments and including details such as specific views for angiography (antero-posterior and lateral for example) or the type of contrast being used.
Intra-procedural imaging	The subsection "Intra-procedural imaging" refers to imaging performed between different steps or devices, to guide them and evaluate their results.

Zywicka EM, Moore AJ, Twine C, et al. Endovascular treatment of peripheral arterial disease: Endo-STAR framework for the design, conduct, and reporting of trials. *Br J Surg*. 2025;112(4):znaf020. doi:10.1093/bjs/znaf020

	In addition to the details provided about the modality, it is important to consider specifying eventual adjuncts such as rulers or road map, especially if those may demonstrate technical advantages in the whole procedure.
Final imaging	The subsection “Final imaging” refers to the imaging performed at the end of the intervention to assess the final result. This is often represented by a final completion angiogram with complete views of the distal arterial tree, but it is important to clearly specify which modality has been used for this assessment with all the relevant details as defined in the framework.

5. INTERVENTION COMPONENTS

5.1.Access	This subsection provides guidance on how to describe access for the intervention. It is suggested to specify the type of access (percutaneous/surgical), the location or more than one location if applicable (anatomical location and if ipsilateral/contralateral or both), whether it is antegrade or retrograde, if the access is image guided (US guided or xray guided) or not, and finally providing details about the sheath being used or specifying if it has not been used. *In pragmatic trials, for example, the research team might decide to leave this step of the intervention at the operator's discretion and not specify or standardise it. In other trials, it might be of interest to evaluate complications related to the point of arterial access, and in this case a careful description of this step might be crucial*.

5.2.Crossing lesion	This subsection provides guidance on how to describe how a lesion is being crossed at the time of intervention. It is important to specify if there is a pre-defined crossing modality such as intraluminal, subintimal, mixed, antegrade or retrograde, and specific crossing techniques. It is suggested to provide further details about the types of wires and catheters, and to specifically provide details about the use of any specific wires (CTO wire) catheters or devices. However, it is recognised that the description and recording of each wire and catheter used for the intervention may not be feasible and realistic.
5.3.Treating lesion	
A. Lesion Preparation	The "lesion preparation" subsection provides guidance on how to describe the steps taken to prepare the lesion for the main intervention. It is proposed to specify whether the lesion preparation is mandatory for all participants, recommended or allowed at the operator's discretion, or required in only specific situations (for example, to allow the passage of devices). The modality of lesion preparation, such as balloon pre-dilatation, atherectomy, intravascular lithotripsy, thrombectomy, or other interventions, should be specified, and further details for each modality should be clarified as proposed in the framework. If the research team does not allow any lesion preparation techniques or devices, this should be clearly specified in the trial protocol. It is suggested to specify how the results of the lesion preparation have been assessed before proceeding with the main intervention. *For example, if in a trial all patients should have a specific lesion preparation decided by the research team, this should be clearly described in the trial protocol, standardised, monitored and reported.*
B. Intervention	The "intervention" subsection provides guidance on how to describe the main intervention performed to treat the lesion.

Zywicka EM, Moore AJ, Twine C, et al. Endovascular treatment of peripheral arterial disease: Endo-STAR framework for the design, conduct, and reporting of trials. *Br J Surg*. 2025;112(4):znaf020. doi:10.1093/bjs/znaf020

	Devices currently available on the market are already included, but it is accepted that newer devices will need to be included in the future. It is acceptable to use one or more devices, as a combination of multiple devices can be required while evaluating complex procedures. It is then suggested to clarify in which order the devices were used, provide specific details for each device as specified in the framework, and clarify if the results were evaluated between each device.
C. Intervention optimisation	The "intervention optimisation" subsection provides guidance on how to describe additional interventions that might be required to improve the result of the intervention. It is suggested to specify which intervention could be required to optimise the intervention, if it is mandatory, recommended or allowed and specify how the results of this step will be evaluated. *For example, a non-fully deployed stent might require a post-dilatation by the trial protocol, while in another trial, the post-dilatation might be considered mandatory for each intervention.*
D. Bailout Intervention	The "Bailout Intervention" subsection provides guidance on how to describe what interventions are acceptable when it is necessary to deal with eventual complications. It is suggested to explain the indications for a bailout intervention, such as flow-limiting dissection, perforation, residual stenosis, vessel spasm, thrombosis or distal embolization. It is proposed to describe which interventions would be acceptable (prolonged balloon inflation, stenting, thrombectomy, thrombolytic or vasodilating agents or other interventions) and which intervention would not be acceptable, and how the results would be re-evaluated. *For example, in a trial evaluating a drug eluting balloon, stenting might be considered an appropriate bailout intervention, but drug eluting stents might not be allowed by the trial protocol.*

Zywicka EM, Moore AJ, Twine C, et al. Endovascular treatment of peripheral arterial disease: Endo-STAR framework for the design, conduct, and reporting of trials. *Br J Surg*. 2025;112(4):znaf020. doi:10.1093/bjs/znaf020

E. Treatment of non-target lesions	The "Treatment of non-target lesions" subsection provides guidance on how to describe concomitant treatment of additional non-target lesions if allowed by the trial protocol. These lesions can be inflow, outflow or other vessels on the same side or the contralateral limb. It is proposed to specify which interventions are permitted and which are not. *For example, in a trial evaluating drug-eluting balloons, it might be acceptable to treat another lesion with a plain balloon, but it might not be allowed to use another drug-eluting device.*
5.4.Closure of artery	The "Closure of artery" section provides guidance on how to describe the final step of the intervention. This can be done with direct external pressure, a closure device or a surgical closure. *It is possible for a research team not to describe and standardise this step, leaving this to the discretion of the operator, while in another trial, it might be appropriate to describe the device being used if, for example, evaluating access complications.*
6. PHARMACOLOGICAL INTERVENTIONS	The "Pharmacological Interventions" section provides guidance on how to describe the pharmacological treatment related to the procedure administered before, at the time and after the procedure. This section does not exhaustively list all drugs the participants might be taking in the perioperative period, as this should still be captured while reporting baseline demographic data.