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Rationale and design of a prospective European multicenter evaluation of the iCover balloon-expandable covered stent as a bridging stent in fenestrated endovascular aortic repair (fenCo)

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ABSTRACT

Background: Fenestrated endovascular aortic repair (FEVAR) is an established treatment for complex abdominal aortic aneurysms involving the renovisceral segment. Long-term durability remains dependent on bridging stent performance, yet prospective device-specific data remain limited. The fenCo study was designed to evaluate the clinical performance and safety of the iCover balloon-expandable covered stent (iVascular) used as a bridging stent during FEVAR.

Methods: fenCo is a prospective, multicenter, open-label, single-arm European clinical investigation conducted in 24 high-volume centers under Regulation (EU) 2017/745. The study aims to include 165 patients undergoing FEVAR for juxtarenal, pararenal, suprarenal, or thoracoabdominal aneurysms using an IFU-compliant fenestrated endograft. All target vessels are bridged exclusively using the iCover balloon-expandable covered stent. Follow-up is planned at discharge, 6 months, and 12 months, with optional extension to 5 years.

Results: The primary efficacy endpoint is bridging-stent patency at 12 months, defined as absence of binary restenosis ($\geq 50\%$ stenosis) or occlusion on imaging. The primary safety endpoint is freedom from target vessel

instability, defined as a composite of aneurysm rupture, target vessel occlusion, component separation, branch-related endoleak, or branch-related reintervention. Secondary endpoints include technical success, endoleaks, reinterventions, mortality, aneurysm sac evolution, and renal outcomes.

Conclusions: fenCo will provide prospective multicenter European data on the safety and performance of the iCover stent used as a bridging stent during FEVAR using predefined imaging-based and clinically adjudicated endpoints. The study is expected to strengthen the evidence base for bridging stent selection in complex endovascular aortic repair.

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Key words: Aortic aneurysm; Abdomen; Endovascular procedures; Endovascular aneurysm repair; Stents; Arteries.

Introduction

Complex abdominal aortic aneurysms involving the renovisceral segment remain a major therapeutic challenge. According to current European Society for Vascular Surgery (ESVS) guidelines,¹ fenestrated endovascular repair (FEVAR) should be the preferred endovascular option in anatomically suitable patients treated in experienced centers.

FEVAR achieves high technical success (>95%) with low early morbidity compared with open repair. However, its long-term durability depends critically on bridging stents, which connect fenestrations to target renovisceral arteries.^{1,2}

Although procedural success is high, reintervention rates after FEVAR remain substantial (27-42% at 3-4 years),³ with a significant proportion related to bridging stent complications including stenosis, occlusion, endoleak, and component separation.^{2, 4-6} Reported target vessel instability ranges from 10-15% depending on definitions and follow-up.^{7, 8}

Several balloon-expandable covered stents have been used in this indication, including Advanta V12 (Atrium Medical Corporation, Hudson, NH, USA; now Getinge, Gothenburg, Sweden),⁹⁻¹¹ BeGraft/BeGraft Plus (Bentley InnoMed GmbH, Hechingen, Germany),¹²⁻¹⁶ and GORE® VIABAHN® VBX (W. L. Gore & Associates, Flagstaff, AZ, USA),¹⁷⁻¹⁹ each with reported favorable mid-term outcomes.

The iCover balloon-expandable covered stent (iVascular S.L.U., Barcelona, Spain) was CE-marked in 2021 for

peripheral arterial applications, including the treatment of atherosclerotic lesions of the iliac and renal arteries and selected aneurysmal or rupture indications, but it does not currently carry a specific labelled indication for use as a bridging stent in fenestrated endovascular aortic repair (FEVAR). Preliminary registry data from Austria and Zurich have demonstrated encouraging early and mid-term observations with high technical success and absence of stent-related occlusion.^{20, 21}

Until the end of 2024, most of them were used off-label but recent regulatory developments have expanded CE-mark indications for several bridging stents, including Advanta V12, BeGraft and Gore VBX, reflecting increasing alignment between clinical practice and device labelling, an important step towards reimbursement pathways.

Against this background, the fenCo study was designed to generate prospective multicentre evidence on the safety and performance of the iCover balloon-expandable covered stent when used as a bridging stent in FEVAR.

Materials and methods

Study design

fenCo is a prospective, open-label, single-arm multicenter European clinical investigation. The study inclusion period will last for 18 months, and completion of enrolment is expected in April 2027 (±6 months) with the completion of the 12-month follow-up in April 2028 (±6 months). Finalization of site agreements and center initiation occurred in February 2026, and the first patient was enrolled on 13 February 2026 at Bordeaux University Hospital.

fenCo involves 24 high-volume vascular centers with established experience in FEVAR across five European countries, France (N.=8), Belgium (N.=7), Germany (N.=6), the Netherlands (N.=2), and Spain (N.=1), thereby ensuring broad geographic representation and supporting external validity (the full list of fenCo investigators is available in Supplementary Digital Material 1: Supplementary Text File 1). The participating centers include both public and private institutions (Supplementary Digital Material 2: Supplementary Table I, Supplementary Figure 1).

Population

Patients ≥ 55 years are eligible if they are undergoing FEVAR for juxta-, para-, suprarenal, or thoracoabdominal aneurysms, in accordance with current indications and guidelines for abdominal aortic aneurysm management. These include aneurysm diameter thresholds exceeding 5.0 cm in women and 5.5 cm in men, or aneurysm growth exceeding 5 mm within 6 months or 1 cm within 1 year (Table I).¹

The fenestrated endograft must be designed so that fenestrations are aligned directly in front of the target vessel ostia, and the distance between the fenestration and the target vessel orifice must not exceed 5 mm. Patients must be strictly compliant with the Instructions for Use (IFU) of the fenestrated endograft selected for implantation. Eligible fenestrated endografts include the Zenith Fenestrated AAA Endovascular Graft (Cook Medical, Bloomington,

IN, USA), the TREO and Anaconda Fenestrated Stent Grafts (Terumo Aortic, Inchinnan, UK).

All target vessels/fenestrations must be bridged exclusively using the iCover balloon-expandable stent platform. Planned use of alternative bridging stents is not permitted. One or up to two stents per fenestration are allowed. Bailout implantation of another bridging stent, if exceptionally required intraoperatively, will be recorded as a major protocol deviation. Aortic angulation at the target vessel level must be $< 45^\circ$. The target vessel must provide a landing zone of at least 10 mm. Eligible target arteries include the renal arteries, the superior mesenteric artery, and the celiac trunk, and must have a diameter between 5 mm and 10 mm. The angulation of the aorta at the level of the target vessels must be less than 45° .

Additional inclusion criteria include documented informed consent with willingness to comply with follow-up evaluations at the specified time points, affiliation to or benefit from a social security system, and an expected life expectancy greater than 12 months.

Clinical exclusion criteria are contraindication to antiplatelet therapy, uncontrolled hematological disorders or heparin-induced thrombocytopenia, chronic or acute aortic dissection, refusal of treatment, pregnancy or intent to become pregnant, emergency treatment or hemodynamic instability, recent myocardial infarction or stroke (< 3 months), unstable angina or New York Heart Association

TABLE I.—Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Age ≥ 55 years	Emergency or ruptured aneurysm
Juxtarenal, pararenal, suprarenal AAA or type IV thoracoabdominal aneurysm	Target vessel stenosis $> 50\%$ or occlusion
Aneurysm meeting guideline-based indication for repair	Thrombus > 3 mm in sealing zone or target artery
Anatomy compliant with IFU of the selected fenestrated endograft	Chronic or acute aortic dissection
Fenestration aligned with target vessel ostium (distance ≤ 5 mm)	Early significant branching of the target vessel risking organ infarction
Target vessel diameter 5–10 mm	Hybrid techniques including branches, semibranches, or chimneys
Target vessel landing zone ≥ 10 mm	Physician-modified endografts or in situ laser FEVAR
Aortic angulation at target vessel level $< 45^\circ$	Bridging stent other than iCover in the target vessel
Renal artery-aortic angle $\geq 30^\circ$	Severe distal outflow disease affecting target vessel patency
Life expectancy > 12 months	Complex iliac access outside the IFU of the selected fenestrated endograft
Written informed consent	Contraindication to antiplatelet therapy
Affiliation to a social security system	Known allergy to cobalt-chromium (L-605) or PTFE
	Recent myocardial infarction or stroke (< 3 months)
	Unstable angina or NYHA class III–IV heart failure
	ASA classification ≥ 5
	Pregnancy or planned pregnancy
	Active infection or mycotic aneurysm
	Participation in another investigational drug or device study

AAA: abdominal aortic aneurysm; TAAA: thoracoabdominal aortic aneurysm; IFU: instructions for use; NYHA: New York Heart Association; PTFE: polytetrafluoroethylene.

(NYHA) class III–IV heart failure, American Society of Anesthesiologists (ASA) classification of 5 or higher.

Anatomical exclusions include target vessel stenosis exceeding 50%, target vessel occlusion, or severe out-flow impairment as these conditions may independently compromise bridging stent durability. In contrast, limited calcification, tortuosity, or mild-to-moderate stenosis that remain technically suitable for standard bridging implantation may be treated with adjunctive predilatation at the operator's discretion. Additional anatomical exclusion criteria include early significant branching from the target vessel associated with a risk of branch coverage and target organ infarction, renal artery-aortic angle $<30^\circ$, thrombus thickness >3 mm within the sealing zone or target arteries, severe peripheral arteriopathy compromising access or distal perfusion, and complex iliac anatomy outside the IFU of the selected fenestrated endograft.

Procedural exclusions are hybrid techniques using branches, semibranches, or chimneys, physician-modified endografts, in situ laser FEVAR; implantation of any bridging stent other than iCover, infectious or mycotic aneurysm, known allergy to stent materials (L-605) and/or polytetrafluoroethylene (PTFE).

Study-related exclusions are participation in another investigational device or drug study that has not completed the entire follow-up period and that may interfere with the results of fenCo are excluded.

Investigational device

The investigational device is the iVascular iCover balloon-expandable covered peripheral stent system. The iCover consists of a balloon-expandable covered stent premounted on an over-the-wire (OTW) delivery system for percutaneous transluminal angioplasty procedures. The stent is intended to be used as a permanent implant and is manufactured from cobalt-chromium alloy (L-605). The stent is completely encapsulated in expanded polytetrafluoroethylene (ePTFE). Each end of the stent includes three tantalum radiopaque markers. The system is mounted on a 0.035-inch OTW balloon delivery platform. The device is available in diameters from 5 mm to 10 mm and catheter lengths of 80 cm to 170 cm, which are compatible with renovisceral target vessels in FEVAR.

The iCover medical device obtained CE approval in 2021. The claimed indications include restoration of atherosclerotic lesions of the common and external iliac arteries and the renal arteries, and treatment of aneurysms, perforations, ruptures, and acute fistulas. The product is approved for these indications when used alone and with-

out combining it with other devices. Use of the latest-generation iCover covered stent as a bridging stent in the specific context of FEVAR is not currently included in the claimed indications. Consequently, clinical data are required to demonstrate safety and efficacy for this specific indication, and the fenCo study is designed to generate the evidence required to substantiate such claims.

Implantation technique

All procedures are performed according to standard FEVAR practice. Bridging stents are deployed between fenestrations and target vessels, and up to two iCover stents per fenestration may be implanted if required. Perioperative antithrombotic management follows current guideline recommendations.^{1, 22}

iCover device sizing is selected by the operator according to fluoroscopic assessment of vessel diameter and lesion length, and the stent diameter is chosen to match the diameter of the reference vessel, while stent length is selected to cover the treated segment, with a slightly longer stent preferred to ensure complete lesion coverage. When access to the lesion is expected to be compromised by small diameter, heavy calcification, or tortuosity, predilatation with an angioplasty balloon may be performed according to the balloon catheter manufacturer's instructions, followed by immediate stent implantation.

For implantation, the proximal end of the guidewire is inserted into the distal tip of the delivery system until the guidewire passes through the straight port of the delivery system connector. The system is then carefully introduced through the introducer under fluoroscopy. After passage through the introducer, fluoroscopy is used to verify that the stent has not been displaced from the radiopaque balloon markers. The iCover stent has three radiopaque markers at each end, and correct positioning requires these markers to remain between the radiopaque markers of the balloon; offset indicates potential stent displacement and necessitates withdrawal of the system together with the introducer as a single unit in accordance with the precautions described in the device documentation. The stent system is advanced over the guidewire under fluoroscopy to the target zone, and correct guidewire exit through the distal tip is confirmed. The stent is positioned across the treated segment using radiopaque markers, and high-resolution fluoroscopy is used to confirm absence of movement or damage prior to deployment. Deployment is performed by progressive inflation using an inflation device, and pressure is maintained until balloon inflation is visualized at both proximal and distal stent ends. Inflation continues un-

til the nominal pressure defined in the compliance chart is achieved, and rated burst pressure is not exceeded because balloon rupture risk increases above this threshold. Optimal expansion requires stent contact with the arterial wall, as inadequate apposition may cause stent displacement during balloon withdrawal. Balloon diameter is selected to be 1:1 or slightly larger than the vessel diameter to account for elastic recoil after deflation, and oversizing is avoided due to dissection risk.

After deployment, the balloon is deflated, and negative pressure is maintained for 15 to 30 seconds depending on balloon size, with the option to perform a swallow maneuver to reinsert the sheath over the balloon and inside the iCover stent. Fluoroscopy is used to confirm complete deflation before catheter movement. With the guidewire maintained across the treated segment, the catheter is withdrawn away from the lesion.

To optimize anchoring between the bridging stent and the fenestration, postexpansion at the fenestration site is recommended by at least 2 mm beyond the fenestration ring size (flaring). If the stent size is insufficient relative to vessel diameter, postdilatation may be performed using the delivery system balloon or a larger, potentially non-compliant balloon. According to the IFUs, stents with diameters from 5 mm to 8 mm may be postdilated with balloons up to 10 mm, while stents with diameters from 9 mm to 10 mm may be postdilated with balloons up to 12 mm, following the manufacturer's recommendations. Angiography is performed to confirm correct stent positioning and target vessel patency. Once angiography confirms adequate dilatation, the guidewire is carefully withdrawn. Closure is performed according to standard practice.

Study endpoints

The primary efficacy endpoint is bridging stent patency at 12 months, defined as the absence of binary restenosis ($\geq 50\%$ stenosis) or occlusion detected on computed tomography angiography (CTA) or angiography at the 12-month visit (± 2 months).

The primary safety endpoint is defined as the proportion of patients without target vessel instability, which is defined as a composite of any branch-related complication leading to aneurysm rupture, death, target vessel occlusion, component separation, or reintervention performed to maintain branch patency or to treat branch-related component separation or endoleak, occurring between implantation and the 12-month (± 2 months). Additional descriptive analyses will be performed at the target-vessel/fenestration level to characterize branch-specific events, includ-

ing restenosis, occlusion, endoleak, component separation, and reintervention.

Secondary endpoints include evaluation of technical success defined as successful introduction and deployment of the iCover stent implanted as bridging stent during FEVAR, assessment of bridging stent patency at the first postoperative imaging and at 6 months and 12 months, assessment of absence of endoleaks related to iCover stent defects (including malposition, rupture, or disconnection) at the first postoperative imaging and at 6 months and 12 months on duplex ultrasound, CTA, or angiography, assessment of absence of reintervention due to technical defects of iCover covered stents between surgery and discharge and between surgery and 6 months and 12 months, assessment of absence of type I or type III endoleaks at the first postoperative imaging and at 6 months and 12 months, assessment of 30-day mortality and in-hospital mortality from all causes, assessment of absence of aortic endograft migration (exceeding 10 mm) at 6 months and 12 months, assessment of aneurysm sac stability defined as no increase exceeding 5 mm in maximum aneurysm sac diameter on CTA at 6 months and 12 months, assessment of absence of postprocedural conversion to open aortic surgery at discharge, 6 months, and 12 months, and assessment of absence of aneurysm-related mortality and aneurysm-related secondary endovascular procedures during follow-up. Secondary objectives also include assessment of absence of major adverse events (defined as aortic rupture, aneurysm-related death, in-hospital death, decline in renal function by at least 20%, lower extremity ischemia, mesenteric ischemia, or unplanned reintervention) at discharge, 6 months, and 12 months, as well as assessment of target vessel patency at 6 months and 12 months and absence of target vessel instability at 12 months. Renal function is assessed preoperatively and at discharge and at 6 months and 12 months. Acute kidney injury is defined according to KDIGO criteria. Chronic renal deterioration is defined as a decline in estimated glomerular filtration rate of at least 20% compared with baseline and/or progression in chronic kidney disease stage. Endpoints are defined as per reporting standards²³ and reported in Table II.

Data collection and follow-up

Patients are followed according to a predefined visit schedule (Supplementary Table I; Figure 1). Data are collected at each protocol visit.

The inclusion and preintervention assessment is performed at visit V0; baseline data include clinical examination and documentation of age, sex, cardiovascular risk

TABLE II.—*Study endpoints.*

Endpoint category	Definition
Primary endpoints	
Primary efficacy endpoint	Proportion of bridging stents without binary restenosis at 12 months (± 2 months), defined as absence of $\geq 50\%$ stenosis or occlusion detected by duplex ultrasound, CTA, or angiography.
Primary safety endpoint	Proportion of patients free from target vessel instability between implantation and the 12-month visit (± 2 months). Target vessel instability is defined as a composite of aneurysm rupture, death, target vessel occlusion, component separation, or reintervention required to maintain branch patency or treat branch-related endoleak or component separation.
Secondary endpoints	
Technical success	Successful introduction and deployment of the iCover bridging stent during FEVAR with preservation of target vessel perfusion.
Bridging stent patency	Patency of the bridging stent assessed at first postoperative imaging, 6 months, and 12 months by CTA, duplex ultrasound, or angiography.
Device-related endoleaks	Absence of endoleaks related to iCover defects (malposition, rupture, disconnection) at postoperative imaging, 6 months, and 12 months.
Reintervention related to iCover	Absence of reintervention due to technical defects of iCover stents between surgery and discharge, and during follow-up at 6 and 12 months.
Type I and III endoleaks	Absence of type I or III endoleaks at postoperative imaging and during follow-up.
Mortality outcomes	30-day mortality and in-hospital mortality from any cause.
Endograft migration	Absence of aortic endograft migration > 10 mm at 6 and 12 months.
Aneurysm sac evolution	Stability of aneurysm sac diameter defined as absence of increase > 5 mm at 6 and 12 months on CTA.
Conversion to open repair	Absence of conversion to open aortic surgery during hospitalization and follow-up.
Aneurysm-related outcomes	Absence of aneurysm-related mortality and secondary endovascular procedures during follow-up.
Major adverse events	Absence of major adverse events including aortic rupture, aneurysm-related death, in-hospital death, renal function decline $\geq 20\%$, lower extremity ischemia, mesenteric ischemia, or unplanned reintervention.
Renal outcomes	Acute kidney injury defined according to KDIGO criteria. Chronic renal deterioration defined as $\geq 20\%$ decline in estimated glomerular filtration rate or progression of chronic kidney disease stage.
Target vessel outcomes	Target vessel patency and absence of target vessel instability at 6 and 12 months.

FEVAR: fenestrated endovascular aortic repair; CTA: computed tomography angiography; KDIGO: Kidney Disease Improving Global Outcomes.

factors, and chronic comorbidities, including renal function, current pathologies and treatments, hemostasis disorders, previous aortic surgery, and factors affecting life expectancy such as heart failure, and cancer. Femoral access is assessed for contraindications or anticipated difficulties, and axillary or brachial access is considered on an optional basis. CTA is performed to assess eligibility according to inclusion and exclusion criteria.

The intervention is performed at visit V1, intraoperative data include details of heparin and antiplatelet therapy, femoral access characteristics and management, and iCover device references and procedural details. Procedural success for both the aortic endograft and the iCover bridging stent is recorded, as are any aortic surgical conversions, lower extremity ischemia, and mesenteric ischemia. Technical characteristics of the procedure, including duration, radiation dose, access routes and difficulties, and any additional dilatation of stented segments, are recorded. Endoleaks of any type and any additional procedures, including access-related interventions and additional target-vessel stenting, are recorded.

Early postintervention evaluation is performed at discharge (visit V2), between 1 day and 7 days postprocedure,

antiplatelet therapy is documented, and femoral access is examined to report local complications. Mortality and cause of death, aneurysm-related or not, are documented, and rupture, reintervention, lower extremity ischemia, and mesenteric ischemia are recorded.

Postoperative imaging is performed with CTA or contrast-enhanced cone-beam computed tomography, with the imaging window extending up to 90 days depending on feasibility. Imaging evaluation includes branch-related complications affecting bridging stents, including binary restenosis, malposition, rupture, occlusion, disconnection, and kinking, as well as fenestrated endograft occlusion, component separation, endoleak classification, aneurysm sac maximum diameter, and femoro-iliac access control.

Follow-up is performed at 6 months postintervention (visit V3, with a ± 2 -month window), and final protocol follow-up is performed at 12 months postintervention (visit V4, with a ± 2 -month window), antiplatelet therapy is documented, eGFR is collected when available, death and cause, rupture, reintervention, lower extremity ischemia, and mesenteric ischemia are recorded. CTA is performed at both visits, and imaging evaluation includes branch-related complications affecting bridging stents, fenestrated endo-

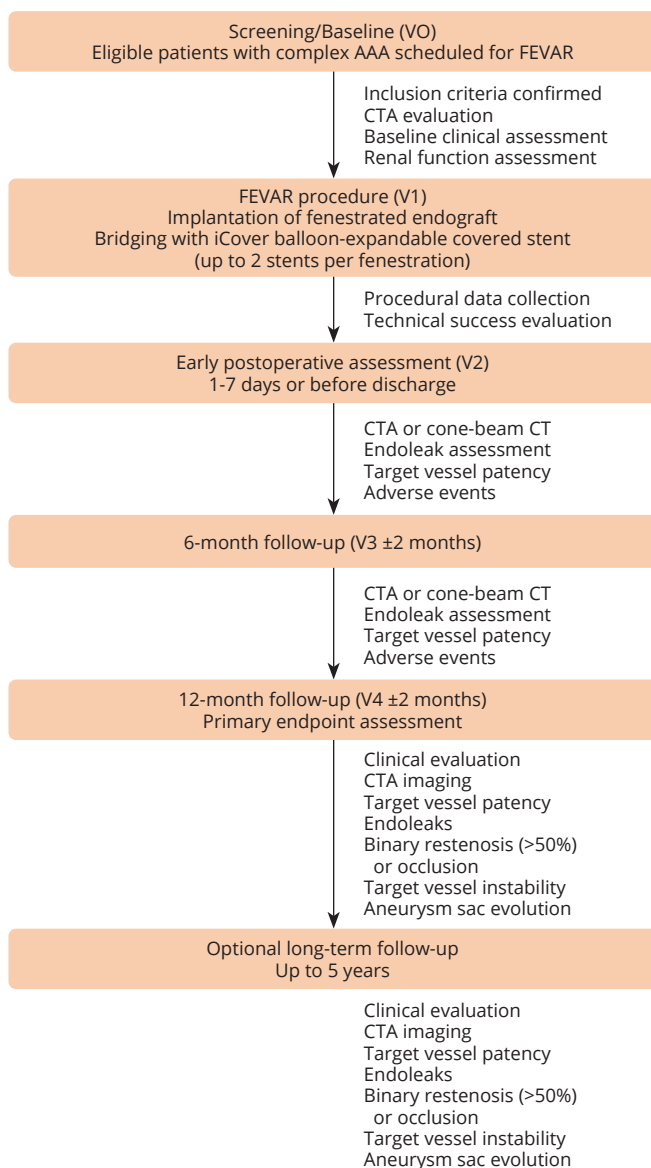


Figure 1.—Flow diagram.

graft occlusion, component separation, endoleak classification, aneurysm sac maximum diameter, and femoro-iliac access control. Adverse events and device deficiencies are collected at all time points as well as estimated glomerular filtration rate (eGFR) when available.

Although the primary analysis is planned at 12 months in accordance with Medical Device Regulation-oriented performance evaluation requirements, the protocol includes a planned extension toward long-term follow-up up to 5 years to assess durability outcomes beyond the first postoperative year.

Imaging analysis

Imaging assessments will be conducted by experienced radiologists, blinded to the study device and procedural details. No independent imaging core laboratory is planned but clinically relevant endpoint events or uncertain imaging findings may undergo additional review by the independent Clinical Event Committee. In addition, a fully automated artificial intelligence–assisted imaging platform (PRAEVAorta®, Nurea, Bordeaux, France), previously validated for aortic and visceral vessel analysis,²⁴ will be used to standardize quantitative imaging measurements across participating centers, with the aim of reducing interobserver variability and improving reproducibility of imaging assessments.

Sample size considerations

Sample size estimation is based on the primary efficacy endpoint, *i.e.* bridging stent patency at the 12-month visit. The number of subjects required was estimated using the exact Clopper–Pearson method based on the expected event rate and desired confidence interval width. Assuming an expected patency rate of 95%, 140 stents are required to describe the primary efficacy endpoint with a 95% confidence level and a confidence interval width of 8%. Allowing 15% missing data, 165 stents are required to meet the primary efficacy objective.

Sample size considerations for the primary safety endpoint, defined as the proportion of patients without target vessel instability between implantation and the 12-month visit, indicate that for a sample of 140 analyzable patients and a hypothesized rate of 90%, the two-sided exact binomial 95% confidence interval would have an estimated half-width of 5.3%, ranging from 83.8% to 94.4%. To satisfy both primary efficacy and safety considerations, 165 patients will therefore be included.

Statistical analysis

Statistical analyses will be performed using R software in a Windows environment, and analyses will be conducted using R language version 4.0.3 or higher. The final analysis is planned after completion of follow-up for the last included patient, in accordance with the sample size calculation. Additional descriptive analyses and interim analysis may be performed if requested.

Analyses will be conducted in predefined populations. The all-subjects population includes all patients who sign informed consent. The intention-to-treat population includes patients from the all-subjects population who are implanted with the investigational device or who undergo

an implantation attempt, including unsuccessful implantation. The per-protocol population includes patients from the intention-to-treat population without any major protocol deviation. Major deviations include missing data for the primary endpoint and non-respect of eligibility criteria. Analyses of baseline characteristics, preoperative and perioperative data, and safety endpoints will be performed on the intention-to-treat population. Efficacy endpoints will be analyzed on both the intention-to-treat and per-protocol populations. Subgroup analyses by technique used and by target vessel type, including renal arteries, will be specified in the Statistical Analysis Plan, and additional subgroup analyses may be defined during study conduct and will be documented in the Statistical Analysis Plan.

Efficacy analyses will be performed at the fenestration/target-vessel level because bridging performance is intrinsically branch-specific. When two iCover stents are implanted within the same fenestration, they will be considered as a single functional bridging unit for analysis purposes. Safety analyses involving clinically relevant composite outcomes will primarily be conducted at the patient level.

For descriptive analyses, quantitative variables will be summarized using mean and median, corrected sample standard deviation, first and third quartiles, minimum and maximum, and confidence intervals derived using Student's *t* distribution, together with the number and percentage of missing data. Qualitative variables will be described using counts and percentages for each category, confidence intervals computed using the Wilson score method with continuity correction or binomial method as appropriate, and the number and percentage of missing data, with population size presented for each table in the statistical report. Confidence intervals will use a two-sided alpha of 5%. Time-to-event outcomes will be analyzed using Kaplan-Meier methods, with survival curves presented together with numbers of events and numbers at risk over time.

No statistical imputation will be applied for missing data. The number of missing data will be presented in each results table, and missing observations will not be considered in the calculation of percentages or in statistical testing.

Safety reporting and event adjudication

All adverse events occurring from implantation to the last follow-up visit are described with time to onset, severity, course, duration, outcome, and relationship to the investigational device and/or procedure. The number and percentage of patients experiencing at least one adverse

event are reported, and events are presented by category, including adverse event, adverse device effect, serious adverse event, and serious adverse device effect. Device deficiencies reported during the study are also described, and the list of adverse events will be annexed to the statistical report.

A monitoring plan is implemented with site visits to control data quality and verify vigilance. A site initiation visit is performed in each center to train the investigating team on study objectives and procedures as described in the clinical investigation plan, to ensure compliance with Good Clinical Practice and to train teams on the electronic case report form. At regular intervals, clinical research associates verify completion and consistency of the electronic case report form data for each center and contact centers by e-mail, telephone, or on-site visits to ensure smooth conduct of the study and resolution of issues. During on-site visits, investigators and collaborators facilitate verification and resolution of data queries and discrepancies, and clinical research associates are mandated to access source records at the center. A close-out visit is performed at each center at study completion.

A Clinical Event Committee composed of three specialists independent of clinical investigation has been established to review and adjudicate safety endpoint events according to a dedicated committee charter, and the adjudication process and responsibilities are defined in this charter.

Ethical statement

The study is conducted in compliance with national regulations in the countries where the investigation is performed, and in accordance with the Declaration of Helsinki and Good Clinical Practice, including ISO 14155:2020. The investigation is conducted under Regulation (EU) 2017/745 and the MDCG 2024-3 guidance on the content of clinical investigation plans for medical devices, and follows the provisions of MDR Article 74(2), as it evaluates a CE-marked device used outside its current intended purpose, it complies with the General Data Protection Regulation (EU) 2016/679. The study received ethical approval from the "Comité d'éthique Ile de France" prior to study initiation, with favorable opinion granted on December 10, 2025. The Authorization was obtained from the French National Agency for Medicines and Health Products Safety (ANSM) on December 3, 2025. The study is registered under ID-RCB/CIV-ID: CIV-FR-25-07-053858 (IDRCB: 2025-A01642-47) and conducted according to the approved protocol version iVascular – fenCo – CIP –

2025-12-11 – v1.3. Written informed consent is obtained from all participants prior to any study-related procedures and for publication of anonymized data. Participant confidentiality is maintained throughout the study, with data anonymized and securely stored. Study findings will be disseminated through peer-reviewed publications and scientific presentations in accordance with ethical and regulatory standards.

Discussion

Bridging stents represent a key determinant of long-term outcomes after FEVAR, with a substantial proportion of secondary interventions driven by branch-level complications such as stenosis/occlusion, disconnection/component separation, and fenestration/branch endoleaks.⁹

A critical limitation of the current literature is the frequent pooling of FEVAR and branched (B)EVAR outcomes, despite important differences in geometry, mechanical stress, and hemodynamic environment. In FEVAR, bridging stents are typically short, straight, and deployed through fenestrations with limited protrusion into the aortic lumen, whereas BEVAR involves longer bridging stents inserted into directional branches, often requiring upper extremity access or steerable sheaths, with increased angulation, longer unsupported segments, and greater mechanical stress over time. These differences directly affect bridging stent durability and limit cross-study comparability.

Historically, the Advanta V12 balloon-expandable covered stent has been one of the most widely used bridging stents in F/BEVAR. In a two-center cohort of 457 fenestrations, device durability was favorable, with freedom from bridging-stent complications of 92% at 3 years and freedom from bridging-stent reintervention of 94% at 3 years;⁹ importantly, although overall reintervention after FEVAR remained frequent, most reinterventions were not directly attributable to the bridging stent. These mid-term data were subsequently complemented by long-term single-center experience in 1,675 target vessels treated in F/BEVAR, showing excellent late outcomes with low rates of target vessel occlusion, endoleak, and reintervention; freedom from target vessel instability at 8 years remained high and was consistently better for fenestrations than for directional branches, underscoring how the configuration (fenestration *versus* branch) and target vessel anatomy can influence durability even with the same bridging stent.¹⁰

Similarly, BeGraft and BeGraft PLUS balloon-expandable covered stents have accumulated an expanding body

of clinical evidence as bridging stents. In the mid-term BeGraft experience, bridging-stent patency was 98% at 1 year and 97% at 2 years, and freedom from secondary procedures on BeGraft bridging stents was 96%, with most events occurring in renal arteries.¹³ More contemporary multicenter experiences and broader F/B-EVAR cohorts suggest similarly good mid-term outcomes for BeGraft and BeGraft PLUS, while consistently reporting higher instability rates in directional branches compared with fenestrations.¹⁵ Moreover, a recent systematic review dedicated to BeGraft bridging outcomes alerts to the low quality of evidence.¹⁶

A specific technical challenge in fenestrated repair is optimization of the seal at the fenestration interface. Proximal flaring is commonly used to improve apposition to the fenestration ring and reduce branch-related type III endoleaks, yet the technique is variable (balloon type, flare diameter, protrusion length, and sequencing), and over-aggressive flaring may theoretically increase local stress or alter hemodynamics. A new dedicated solution, the Be-Flared, aims to standardize this step. Early experience has been reported, and early prospective multicenter data have also begun to emerge.^{25, 26}

Finally, the GORE VBX balloon-expandable endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ, USA) has also emerged as an important bridging stent in F/BEVAR. Studies have reported encouraging short- and mid-term outcomes, with high technical success and primary patency rates, and low rates of branch-related reinterventions, although type Ic endoleaks and branch instability remain recognized concerns, particularly in complex target vessel anatomy.¹⁷⁻¹⁹

Balloon-expandable covered stents differ in radial force, foreshortening behavior, flare capability, radiopacity and conformability in angulated anatomy. The iCover balloon-expandable covered stent is CE-marked for peripheral arterial indications, including renal arteries, and has design characteristics that may be attractive for renovisceral bridging, including cobalt-chromium construction, full ePTFE encapsulation, and three tantalum radiopaque markers to enhance visibility during deployment. The device also allows postdilatation beyond nominal diameters within manufacturer-recommended limits thanks to its open-cell design, enabling controlled proximal “flaring” strategies to optimize fenestration apposition when used as a bridging stent, which is explicitly standardized and described in the fenCo procedural approach. Compared to Advanta V12 (stainless steel platform) and BeGraft and Gore VBX (cobalt chromium platforms), iCover may of-

fer favorable visibility and expansion characteristics in selected anatomies, although these theoretical advantages require prospective validation.

Importantly, studies contributing to the regulatory and reimbursement landscape for these bridging stents have been predominantly retrospective or prospective single-arm cohorts and frequently allowed a mix of bridging stents across all target vessels without strict standardization of flaring techniques, imaging follow-up schedules,²⁷ or end-point definitions and adjudication (e.g., binary restenosis thresholds, definitions of “instability”, and adjudication of type IIIc branch endoleaks), which may introduce heterogeneity when interpreting device-specific performance.¹¹ In addition, inclusion criteria regarding proximal sealing within the target vessel and fenestration alignment were not always uniformly defined, with some studies accepting shorter sealing zones (as low as 5 mm), and bridging stent-level outcomes are influenced by multiple interacting variables such as target vessel diameter and calcification, aortic/branch angulation, fenestration–ostium distance and alignment, the degree and method of proximal flaring, and operator-specific practices which complicates indirect comparisons between stent platforms, which may influence long-term durability outcomes. In contrast to most previously published series, the fenCo study is designed to evaluate a single bridging stent (iCover) across all target vessels, thereby providing a “pure” assessment of device performance without confounding from mixed-device strategies.

To date, clinical data for iCover as a bridging stent in FEVAR come mainly from observational experiences. In the Austrian national registry,²⁰ iCover demonstrated high technical success and low early branch-related complication rates when used for renovisceral bridging in FEVAR. A Zurich single-center registry similarly reported satisfactory technical success and short- to mid-term target vessel stability.²¹ These signals are encouraging but do not replace prospective multicenter evidence with prespecified endpoints and uniform follow-up windows. Furthermore, these early datasets were limited by relatively short follow-up durations and heterogeneous imaging protocols, which reinforces the need for a standardized evaluation framework. fenCo is therefore designed to address a concrete evidence gap: generating regulatory-grade, device-specific performance and safety data in a multicenter European setting using predefined criteria, including CTA-based assessment of binary restenosis-free patency and a clinically meaningful composite definition of target vessel instability. In addition, the study specifically focuses on FEVAR,

thereby avoiding the confounding effects associated with pooled F/BEVAR analyses and enabling a more accurate assessment of bridging stent behavior in the fenestrated configuration.

Limitations of the study

The principal limitation of fenCo is the single-arm design, which precludes direct randomized comparison with alternative bridging stents. Nonetheless, in the current landscape—where multiple devices are in use, anatomy is highly heterogeneous, and bridging strategies are strongly operator-dependent—a prospective single-arm investigation remains an appropriate step to generate robust device-specific evidence. The study’s composite safety endpoint of target vessel instability is clinically relevant but may be influenced by center-level thresholds for reintervention; the planned Kaplan–Meier analyses and time-to-event reporting of the individual components should partly mitigate this by providing transparency on event timing and nature. Another limitation is the absence of an independent imaging core laboratory, which may introduce inter-center variability in imaging interpretation. However, this risk is expected to be mitigated by the use of prospectively standardized imaging protocols, blinded radiological assessment, independent Clinical Event Committee adjudication when required, and the use of a fully automated artificial intelligence–assisted imaging platform (PRAEVAorta®) to standardize quantitative measurements across centers.

Conclusions

fenCo is the first prospective European multicenter study specifically designed to evaluate the iCover balloon-expandable covered stent used exclusively as a bridging stent during FEVAR. By avoiding the use of mixed bridging stents, the study will provide device-specific real-world data on bridging stent performance. The multicenter design will allow comprehensive assessment of key FEVAR durability outcomes, including target vessel stability, bridging stent patency, and aneurysm sac exclusion. These results are expected to strengthen the clinical evidence base for bridging stent use in complex endovascular aortic repair and may contribute to both clinical practice optimization and future regulatory alignment.

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Conflicts of interest

Eric Ducasse has received research funding from iVascular (fenCo study sponsor), research support from Cook, Terumo Aortic, Siemen and Gore; has financial interests with Cook, Terumo Aortic, Siemens, and Gore; and received honoraria from Cook, Terumo Aortic, Siemens, and Gore. Caroline Caradu received research support from Terumo Aortic, Asahi, Biotronik, Medtronic, Shockwave, and Boston Scientific, and has financial interests with Terumo Aortic, Asahi, Biotronik, Medtronic, Shockwave, and Boston Scientific.

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Data availability

The data associated with the paper are available from the corresponding author upon reasonable request.

Manuscript registration

This study was registered under registration number ID-RCB/CIV-ID: CIV-FR-25-07-053858 (IDRCB: 2025-A01642-47).

Ethical approval

All procedures performed in this study involving human participants received ethical approval from the competent authorities, as described in the appropriate section of the manuscript, and have been conducted in accordance with the 1964 Helsinki Declaration and its later amendments. The authors confirm that this article does not report any studies involving embryos, gametes and human embryonic stem cells conducted by the authors. The authors confirm that this article does not report any studies involving animals conducted by the authors.

Informed consent

Written informed consent was obtained from all participants prior to inclusion in the study and for publication of their data, as described in the appropriate section of the manuscript.

Authors' contributions

Eric Ducasse and Caroline Caradu have given substantial contributions to the study conception and design of the manuscript and to the manuscript draft; other authors revised it critically. All authors read and approved the final version of the manuscript.

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SUPPLEMENTARY DIGITAL MATERIAL 1

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SUPPLEMENTARY DIGITAL MATERIAL 2

Supplementary Table I.—Data collection plan.

	V0	V1	V2	V3	V4
	Inclusion	Intervention	Discharge	6 months post intervention	12 months post intervention
Eligibility criteria	X				
Informed consent form	X				
Age, gender	X				
Cardiovascular risk	X				
Chronic pathologies	X				
Indication and location	X				
Angio CT scan	X			X	X
Angio CT scan or Injected CBCT			x up to 90 days		
Renal function clearance	X		X	X	X
Heparin and antiplatelet therapy		X	X	X	X
Data on intervention		X			
Successful introduction and deployment of the iCover stent and endograft		X			
Aortic surgical conversion		X			
Lower extremity ischemia		X	X	X	X
Mesenteric ischemia		X	X	X	X
Death			X	X	X
Rupture			X	X	X
Reintervention			X	X	X
Adverse events		X	X	X	X
Device deficiencies		X	X	X	X

Supplementary Figure 1.—Participating centers.

