The first prospective safety and effectiveness trial of the excimer laser assisted nonocclusive anastomosis system in coronary artery bypass grafting

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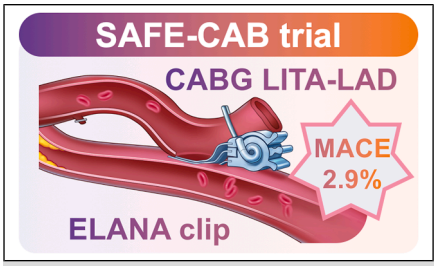
ABSTRACT

Objective: Coronary artery bypass surgery (CABG) is the most common technique in cardiac surgery. Distal anastomoses are currently almost exclusively hand-sewn, which limits the widespread implementation of less-invasive approaches. The aim of this trial is to investigate the safety and effectiveness of the excimer laser-assisted nonocclusive anastomosis (ELANA) device to construct distal anastomoses in CABG.

Methods: This study is a single-center, single-arm, prospective trial. Eligible patients were included from June 2023 to August 2024. The left internal thoracic artery (LITA) to left anterior descending (LAD) anastomosis was constructed using the ELANA anastomotic system, with additional hand-sewn anastomoses if required. The primary outcome was device-related major adverse cardiac events (MACE; consisting of cardiac death, and myocardial infarction [MI] or repeat revascularization of the LAD territory) at 1 year. Secondary outcomes included 6-month LITA patency assessed by coronary angiography defined by FitzGibbon (FG) criteria and 1-year overall MACE (composite death, MI, and repeat revascularization of all coronary artery territories).

Results: In total, 71 patients (89% male, aged 71.0 ± 6.5 years) were included. One-year device-related MACE was 2.9%, consisting of cardiac death and MI due to LITA failure, whereas overall MACE was 8.7%. Six-month LITA patency was 92.5%: FG criteria A 40.6%, B 51.6%, and O 7.8%. Intravascular ultrasound was performed in 6 patients with FG B, which revealed no significant stenosis.

Conclusions: This trial demonstrates the safety and effectiveness of the ELANA device, but long-term follow-up is needed to confirm this. Trials are needed to investigate whether this device facilitates less-invasive approaches in CABG. (J Thorac Cardiovasc Surg 2026;■:1-9)



***LITA*, Left internal thoracic artery; *LAD*, left anterior descending coronary.**

CENTRAL MESSAGE

The excimer laser-assisted anastomotic system is a safe and feasible device to facilitate sutureless coronary anastomosis confirmed by 1-year device-related MACE of 2.9% and overall MACE of 8.7%.

PERSPECTIVE

Widespread evolution to minimally invasive techniques in coronary bypass grafting have been limited by the technical difficulty of the distal anastomosis. This study confirmed the safety and feasibility of the ELANA device, which could potentially enable wider application of less-invasive approaches in coronary surgery. Future clinical trials are currently underway.

See Commentary on page XXX.

ADULT

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Abbreviations and Acronyms

CABG = coronary artery bypass grafting
CT = computed tomography
ELANA = excimer laser-assisted non-occlusive anastomosis
FG = FitzGibbon
IVUS = intravascular ultrasound
LAD = left anterior descending
LITA = left internal thoracic artery
LVEF = left ventricular ejection fraction
M = medium
MACE = major adverse cardiac events
MI = myocardial infarction
Mx = medium extended
PCI = percutaneous coronary intervention

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Coronary artery bypass grafting (CABG) is the most frequently performed and among the most successful forms of cardiac surgery. Anastomoses worldwide are currently almost exclusively hand sewn.[1,2] Although less-invasive approaches are feasible, widespread implementation is mainly limited as the result of the technical complexity of suturing the distal anastomosis. Although previous sutureless devices such as C-Port were associated with a short learning curve, they were eventually withdrawn because of several technical limitations.[3]

The excimer laser-assisted nonocclusive anastomosis (ELANA) technology was originally developed for neurovascular bypass procedures and was successfully implemented in clinical practice.[4,5] Subsequent studies in porcine models for CABF demonstrated technical feasibility for its use in performing distal anastomosis. High 6-month patency rates and favorable histologic findings, including neoendothelialization without local hyperproliferation, were demonstrated.[6] On the basis of these preclinical data, this first prospective clinical trial was initiated to evaluate the safety and effectiveness of the ELANA heart bypass system in patients undergoing coronary artery bypass grafting (SAFE-CAB trial).

METHODS

Trial Design and Study Population

The SAFE-CAB trial was a single-center, single-arm, prospective study performed in the St Antonius Hospital (Nieuwegein, the Netherlands). Institutional review board approval was obtained on January 27, 2022 (registration number L22.003), approval from the Medical Ethics Committee was obtained in July 2021 (R20.009), and the trial was registered at ClinicalTrials.gov (NCT07005843) and on July 28, 2021, in the German Clinical Trial Register (DRKS00020545). The study was conducted in accordance with the Declaration of Helsinki (2013), the European regulation on medical devices (2017/745), ISO 14155, ISO 14971, and local regulations.

Patients determined eligible for nonemergent CABG including the left anterior descending (LAD) by the Heart Team were included if they were at least 18 years of age, willing and able to give written informed consent, and to comply with follow-up evaluations. Exclusion criteria were previous or planned concomitant cardiac surgery, active smoking, pregnancy, female patients of childbearing potential who were not using contraception, left ventricular ejection fraction (LVEF) <30%, dialysis, coagulopathy, planned other interventional procedure within 1 month, cerebrovascular accident within 3 months before surgery, or contraindication for left internal thoracic artery (LITA) harvest. During surgery, additional exclusions could be made in accordance with the instructions for use of the ELANA anastomotic system, specifically a diffusely calcified anterior wall of the LAD, intramyocardial LAD, or a diameter of the target vessel incompatible with the medium ELANA clip ($\leq$1.94 mm).

All trial data were entered in secure electronic case report forms (Greenlight Guru) and subjected to 100% monitoring by a clinical research organization (HEMEX ag.). An independent Data Safety Monitoring Board, comprising an independent cardiologist, cardiothoracic surgeon, and statistician, assessed safety every 3 months and approved continuation of the trial on the basis of these findings. Coronary angiographies were assessed by an independent core laboratory (Cardialysis) using Rubo DICOM Viewer 2.0 (Rubo Medical Imaging) and CAAS 8.5 (Pie Medical Imaging). Intravascular ultrasound (IVUS) pullbacks were assessed by the same core laboratory using Medis QIvus 3.1 (Medis Medical Imaging Systems bv). Angiographic assessments included percentage of diameter stenosis (visually or by quantitative coronary angiography) and graft functionality and patency using the Fitzgibbon (FG) classification. For IVUS analyses, the anastomosis frame was used as center of the analysis region. When available, the regions 5 mm distal and proximal to both parts of the anastomosis were analyzed, adding up to an analysis region of 10 mm.

Surgical Procedure

Before the SAFE-CAB trial, the 2 participating surgeons (each with more than 10 years of experience) received extensive product training in ex vivo and in vivo porcine models to be qualified to use the ELANA technique. The ELANA anastomotic system requires several accessories

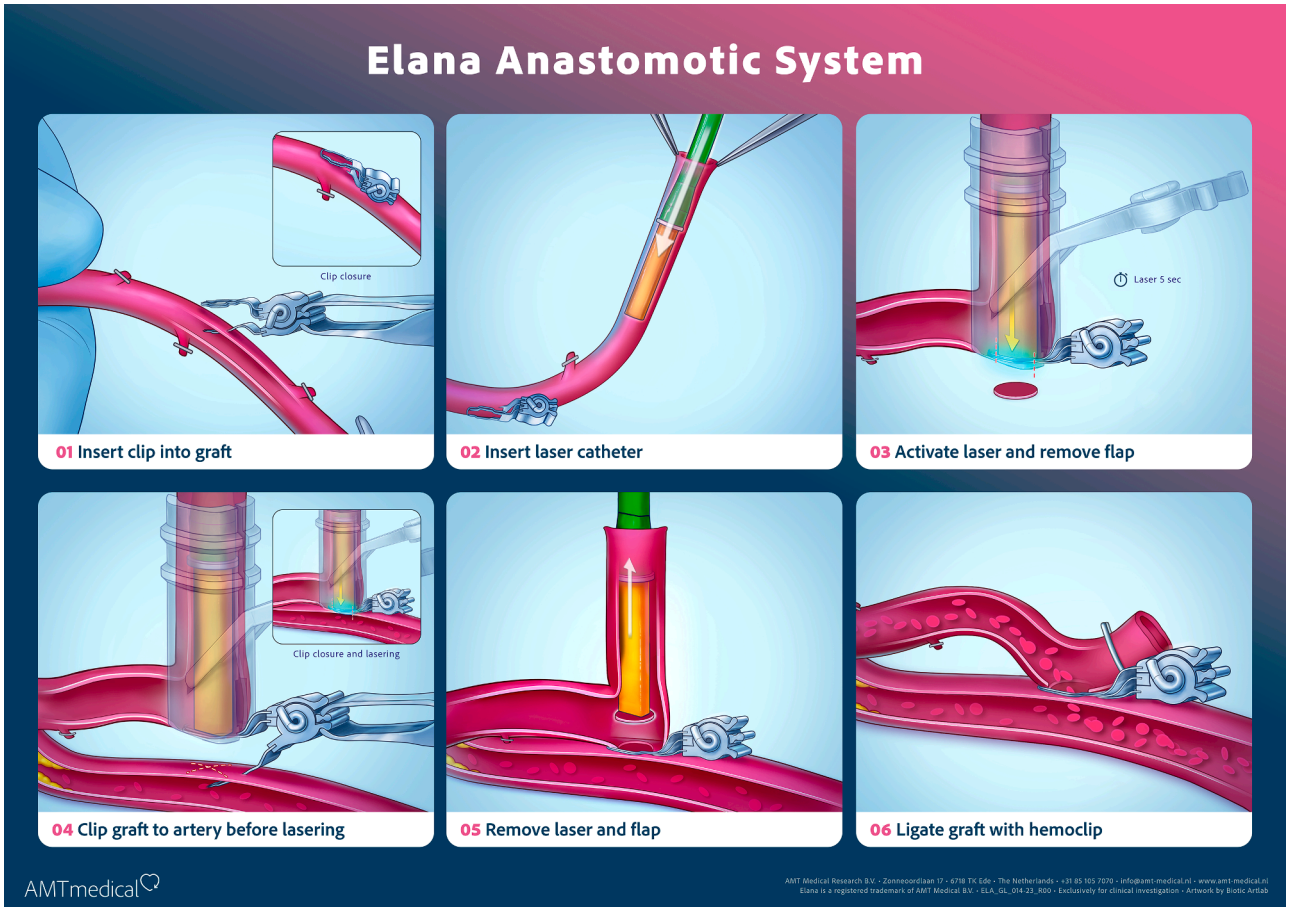

FIGURE 1. The 6-step principle of the ELANA anastomotic system. *ELANA*, Excimer laser-assisted non-occlusive anastomosis.

and an established step-by-step procedure (Figure 1), of which a detailed description including a video has previously been published.[7] Surgery was performed via median sternotomy according to standard practice. Patients received an LITA-to-LAD anastomosis with the ELANA system, either in an off-pump or pump-assisted setting. Initially, a Medium (M) laser catheter was used to create the arteriotomy, which was in the second half of the trial replaced by the Medium Extended (Mx) laser catheter, which has a thinner laser tip to facilitate easier insertion into the distal end of the LITA. Additional sutured grafts were constructed if needed. Transit time flow measurements were performed to assess bypass patency in all grafts. Adequate flow was defined as a pulsatility index <5. Patients received dual antiplatelet therapy from postoperative day 1 for 6 months, as would be recommended after percutaneous coronary intervention (PCI).[8]

Study End Points and Follow-up

Technical success was defined as successful ELANA anastomosis creation and complete flap removal at the intended anastomotic site with adequate bypass flow. Procedural success was defined as composite of technical success, absence of anastomosis leakage or need for conversion to sutured anastomosis and absence of graft failure and myocardial infarction (MI). Clinical follow-up visits and additional examinations were scheduled at 2 days postoperatively, at discharge, and at 1 month, 6 months, and 1 year after surgery (Figure 2). During admission and at every follow-up visit, adverse events were reported. The prespecified primary outcome was device-related major adverse cardiac events (MACE), a composite of cardiac mortality, MI in the territory of the LAD, and repeated LAD revascularization at 1-year follow-up (definitions in Table E1). Follow-up for the primary outcome was finished March 2025. Secondary outcomes included 6-month patency assessed by coronary angiography using the FG criteria: FG A (excellent), FG B (lumen narrowing of 50% or more of the graft vessel or of the coronary artery impairing flow), and FG O (occluded).[9] In patients in whom coronary angiography could not be performed, computed tomography (CT) enabled the assessment of patency (Figure 3). Lastly, 1-year overall MACE was assessed as a composite of cardiac mortality, MI, and repeat revascularization of all coronary artery territories.

							Follow-up Visits				
	Pre-Screening	Screening/enrolment	Pre- Surgery	Surgery	POD 2 (1)	Discharge (2)	POD 30	POD 180	POD 365	POD 730	USV/ ETV (3)
Visit number	**0**	**1**	**2a**	**2b**	**3**	**4**	**5**	**6**	**7**	**8**	**-**
Patient Information Sheet	•	•									
Informed Consent		•									
Inclusion / Exclusion Criteria		•	•								
Demographics, Medical and Surgical history		•									
Physical Examination / Vital Signs		•	•		•	•	•	•	•	•	•
Pregnancy Test (female patients of child-bearing potential only)		•	•				•	•	•		•
Renal Test			•			•					
Coagulation Test			•								
Cardiac Biomarkers			•	•							
Antiplatelet and Anticoagulation Therapy Management			•	•							
Intra-operative Data				•							
Post-operative Assessment						•					
Pain Assessment					•	•	•				
Graft Patency (Angiography)			•					•			
LVEF (Transthoracic Echocardiography)			•			•	•	•			
QoL Assessment (SF-12 & SAQ-7)		•					•	•	•		
ECG/ Stress ECG		•	•	•	•	•	•	•	•	•	•
Post-Wound Healing					•	•	•				
Adverse Event Reporting (AEs, SAEs, MACEs)				•	•	•	•	•	•	•	•
Device Deficiency Reporting				•							
Concomitant Medication		•			•	•	•	•	•	•	•
Reason for Early Study Termination (ETV only)											(•)

(1) If discharge occurs on POD 2 or before, the assessment will be completed as per the discharge visit and on the discharge eCRF page.
(2) If discharge occurs between 25 to 45 days post-operative, the assessments will be completed on POD 30 eCRF page and the discharge assessment visit will be skipped
(3) USV - Unscheduled Visit. ETV - Early Termination Visit

FIGURE 2. Study schedule of assessments and follow-up. *POD*, Postoperative day; *USV*, unscheduled visit; *ETV*, early termination visit; *LVEF*, left ventricular ejection fraction; *QoL*, quality of life; *ECG*, electrocardiogram; *AE*, adverse event; *SAE*, serious adverse event; *MACE*, major adverse cardiac event.

Statistical Analysis

Using pooled data from the 12-month follow-up publications of the C-Port system (proportion freedom of MACE 95.24% [140/147]), a sample size of 60 patients was calculated using the Farington and Manning likelihood score test with a power of 95%, a one-sided alpha of 0.025, and a non-inferiority margin of 10%.[10,11] Sample size was increased to 82 to account for expected drop-outs resulting from noncompliance, death, or intraoperative reasons. The primary end point is represented as proportion, and comparison with the pooled data from C-Port system are performed using the Fisher exact test.

Statistical analysis was performed on intent-to-treat principle by an independent statistician using R, version 4.5.2 (R Core Team (2025; R: A Language and Environment for Statistical Computing; R Foundation for Statistical Computing). Missing data were not imputed for any safety or effectiveness end points. Analyses were performed using complete case data, meaning that only patients with available information for the respective end point were included. Patients without an implant clip at the end of the surgery, missing assessment information, or lost to follow-up were therefore excluded from the primary outcome and patency analyses. The sample size used for each analysis is reported accordingly. With the introduction of a new laser catheter model, subgroup analysis was performed on the basis of the catheter type as requested by the ethical committee, using the Cochran-Armitage trend test.

RESULTS

Patient Characteristics and Operative Findings

Informed consent was obtained from 90 patients between June 2023 and September 2024. After screening and intraoperative assessment of the target vessels, 83 patients met the inclusion criteria (Figure 4). Mean age was 71.0 ± 6.5 years, 89% were male, and they had a mean body mass index of 27.6 ± 3.9 kg/m^2. Among enrolled patients, 40% had

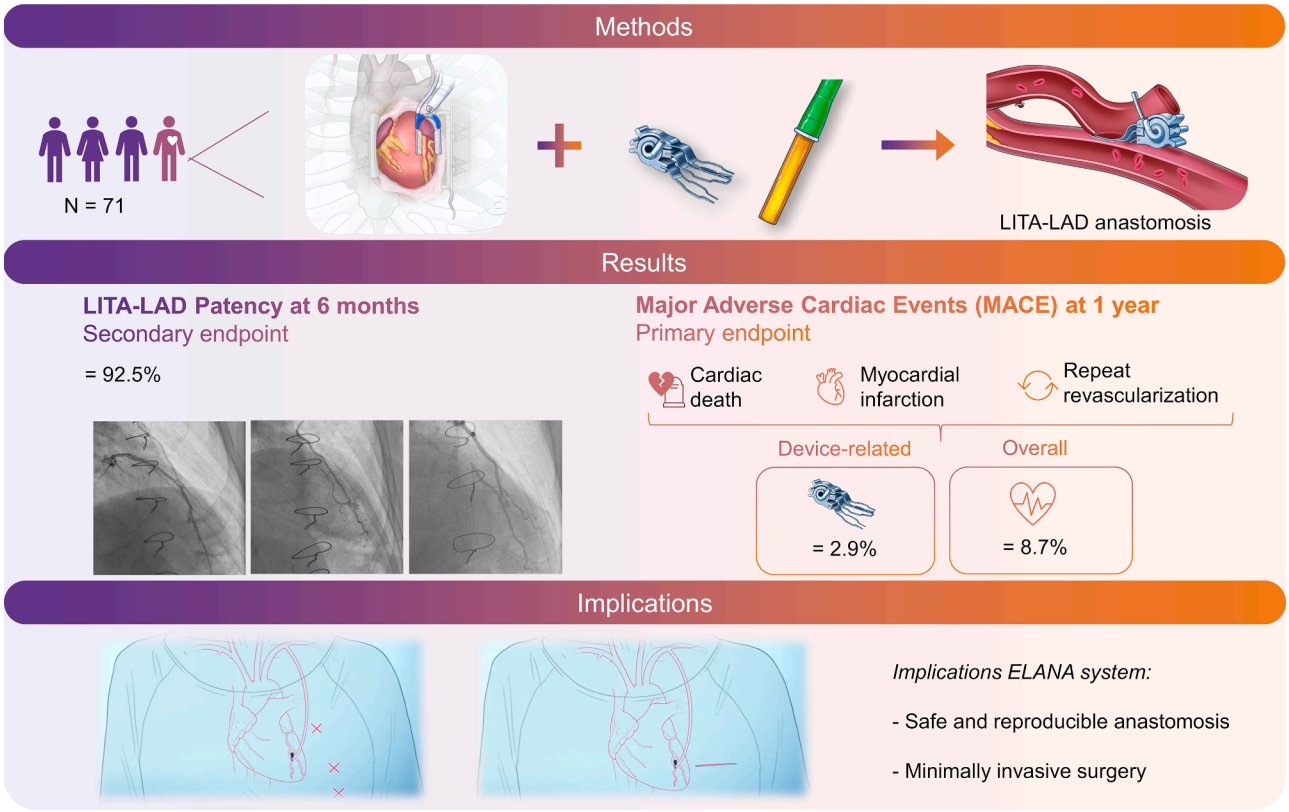

FIGURE 3. Summary of study methods, results, and implications. *ELANA*, Excimer laser-assisted nonocclusive anastomosis; *LITA*, left internal thoracic artery; *LAD*, left anterior descending coronary artery.

diabetes and 48% had a history of smoking. Mean LVEF was 52.2, and 24.1% of patients had undergone previous PCI. European System for Cardiac Operative Risk Evaluation II was 1.29% (Table 1). Intraoperatively, 6 patients were excluded because of anatomical considerations: intramural calcified LAD (n = 1), LAD insufficient diameter for clip (n = 3), and LITA too small for laser catheter (n = 2, both M-catheter). Conversion from ELANA to sutured anastomosis was required in 12 patients because of insertion of the clip into the LAD vessel wall (n = 2), incomplete LAD flap retrieval (n = 3), insufficient diameter of the target vessel (n = 2), mechanical dislocation of the anastomosis during final step of the ELANA procedure (n = 2), or dubious transit time flow measurements (n = 3; in 2 cases flow remained similar after conversion due to competitive flow), leading to 87.8% technical and 86.5% procedural success. One mechanical dislocation occurred during sudden and unannounced lung recruitment using high volume and pressure ventilation by the anesthesiologist during transit time flow measuring of the LITA, pushing the flow probe with the LITA away from the LAD, partially tearing off the anastomosis. The second dislocation was during closure of the distal end with a vascular clip during which the surgeon was jostled leading to traction on the LITA, tearing the anastomosis. Conversion to sutured anastomosis using the LITA was possible in all cases by using the laser-excised anastomotic opening in the LAD. In total, 71 patients received a LITA-ELANA-LAD anastomosis. The majority was performed to the mid-LAD (n = 43, 60.6%) and in 20.5% an additional haemostatic suture was required. At the intended anastomotic site, the LAD diameter was 2.35 ± 0.33 mm and LITA diameter was 2.69 ± 0.38 mm. Mean LITA flow after weaning extracorporeal circulation was 39.0 ± 19.8 mL/min, with a pulsatility index of 1.6 ± 0.7 and 69.1 ± 8.0% diastolic filling. Mean total number of distal anastomoses performed was 3.5. In addition to the LITA-LAD anastomosis, 176 other distal anastomoses were constructed (venous n = 170, right internal thoracic artery n = 3, radial artery n = 3). Complete revascularization was achieved in all patients.

Primary Outcomes

Three patients were lost to follow-up before the primary end point due to noncompliance to the required study visits (n = 2) or death (n = 1, was included as MACE). One-year device-related MACE was 2.9%. The first MACE was a non-ST elevation MI due to LITA-LAD occlusion at the

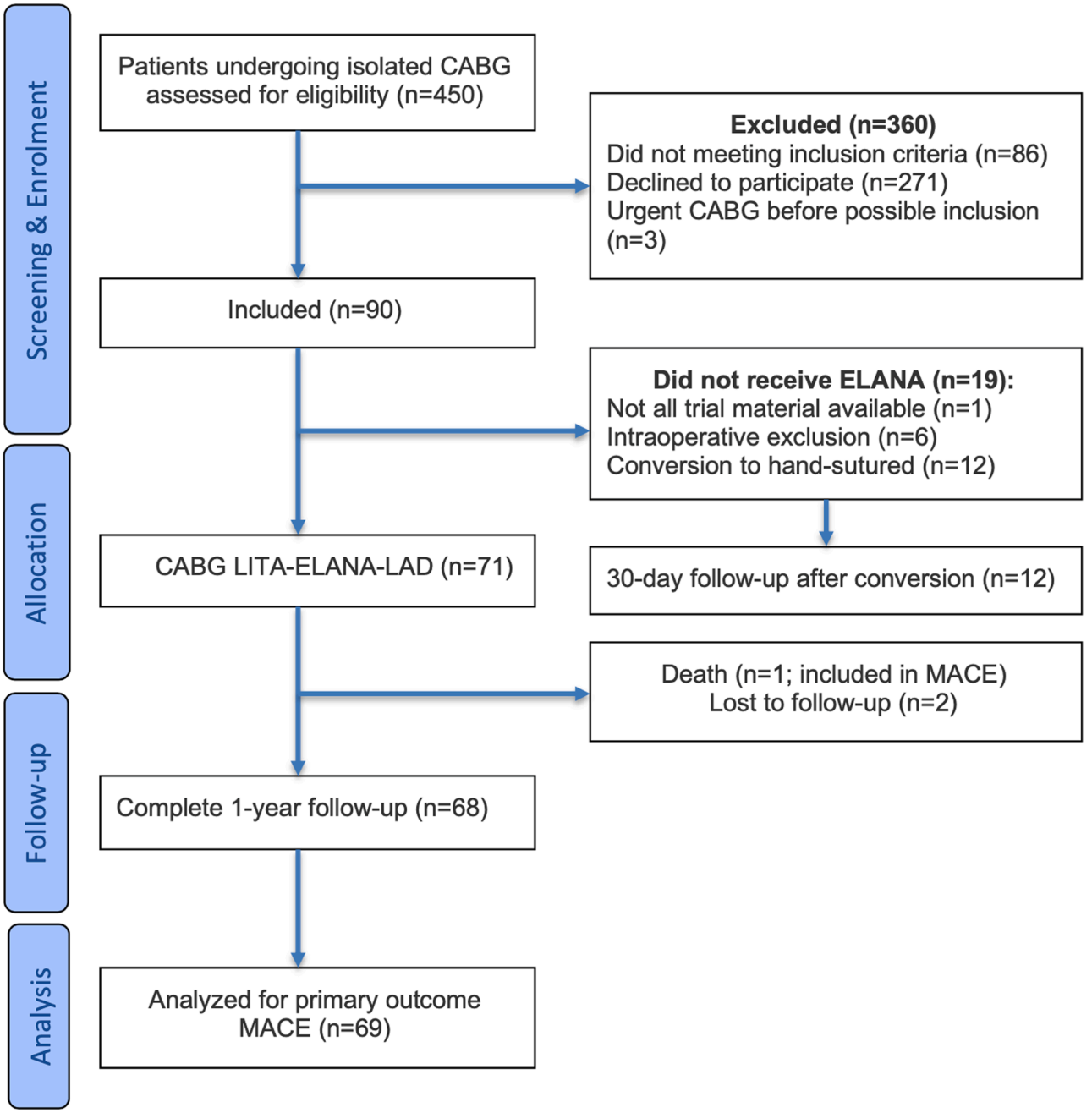

FIGURE 4. Trial flow diagram. *CABG*, Coronary artery bypass grafting; *ELANA*, excimer laser-assisted nonocclusive anastomosis; *LITA*, left internal thoracic artery; *LAD*, left anterior descending coronary artery; *MACE*, major adverse cardiac event.

anastomotic site at 111 days postoperative. A PCI of the LAD was performed (M-catheter group), with stent placement at the site of the LAD stenosis and balloon dilatation of the LAD at the anastomotic site, during which the interventional cardiologist experienced no difficulty. After PCI, the patient was revealed to be a cytochrome P2C19 intermediate metabolizer and subsequently received ticagrelor instead of clopidogrel. Transthoracic echocardiography showed good LVEF without regional wall abnormalities. The patient did not experience any MACEs or angina afterwards and is doing very well clinically. The second MACE was cardiac death at 105 days after surgery during readmission for right-sided heart failure of unknown cause without any signs of ischemia or infarction in a 78-year-old patient (Mx-catheter). No angiographic graft evaluation was performed. The noninferiority end point was met (ELANA 97.10% vs C-Port 95.24% freedom from 1-year device-related MACE, $P = .0033$).

TABLE 1. Baseline characteristics

Characteristic	Patients (n = 83)
Age, y	71.0 ± 6.5
Female sex	9 (10.8%)
BMI	27.6 ± 3.9
LVEF	52.2 ± 7.7
History of smoking	41 (49.4%)
Hypertension	56 (67.5%)
Peripheral arterial disease	2 (2.4%)
Renal dysfunction	3 (3.6%)
Previous MI	7 (8.4%)
Previous PCI	20 (24.1%)
Previous cerebrovascular accident	4 (4.8%)
EuroSCORE II	1.29 ± 0.71
Number of diseased coronary arteries	
One vessel	5 (6.0%)
Two vessels	21 (25.3%)
Three vessels	57 (68.7%)

Values are shown as n (%) or mean ± SD. *BMI*, Body mass index; *LVEF*, left ventricular ejection fraction; *MI*, myocardial infarction; *PCI*, percutaneous coronary intervention; *EuroSCORE II*, European System for Cardiac Operative Risk Evaluation.

Secondary Outcomes

Overall, 6-month patency was assessed in 67 patients (64 angiography and 3 CT; 94.4%); 1 patient died before undergoing imaging, 1 CT scan was of insufficient quality to determine patency, and 2 patients refused both coronary angiography and CT. LITA-LAD patency was 92.5%. Further assessment of the patients who underwent coronary angiography using the FG criteria showed FG A in 40.6% (26/64), FG B in 51.6% (33/64), and FG O in 7.8% (5/64). IVUS was performed in 6 patients with FG B at the discretion of the interventional cardiologist performing the CAG, confirming the absence of significant stenosis (Figure 5, Table E2). Subgroup analysis revealed a tendency for greater patency in the Mx-catheter group, which did not reach statistical significance (85.2% M-catheter vs 97.5% Mx-catheter; $Z = 1.75$, $P = .079$).

The overall patency of additional bypass anastomoses was 92.5% (149/161). Overall 1-year MACE was 8.7%, comprising the 2 primary end point events, one non-ST elevation MI of the right coronary artery requiring PCI, 1 ST elevation MI due to diagonal branch occlusion in the immediate postoperative period treated with balloon-dilatation, and 2 elective PCIs of the obtuse marginal branch and the right coronary artery for chronic coronary syndrome following graft occlusion. If conversion to sutured anastomosis was performed, patients were followed up to 30 days postoperative. No MACE were observed in this group.

DISCUSSION

This trial demonstrates the safety and effectiveness of the ELANA system for CABG surgery, but long-term follow-up is needed to confirm this. The 1-year device-related MACE was 2.9%, and the noninferiority end point was met (C-Port 1-year freedom from MACE: 95.24%). One of device-related events in the SAFE-CAB trial concerned an occluded LITA-LAD anastomosis. A contributing factor could be that this patient was a cytochrome P2C19 intermediate metabolizer, possibly resulting in less-effective antiplatelet therapy, which could lead to anastomosis occlusion due to direct contact of the metal clip to the circulation. After this event, cytochrome P2C19 metabolizer status was determined in every patient and anticoagulation was tailored if required. No further MIs occurred. The second patient died from right-sided heart failure without signs of ischemia, potentially overestimating the device-related event rate.

The overall 1-year MACE rate of 8.7% aligns with rates reported by other trials. Two on-pump versus off-pump CABG trials reported overall MACE rates—composed of death, MI, and repeat revascularization—of 8.1% and 8.7% at 1 year.[12,13] The PRAGUE trial comparing on-pump and off-pump surgery reported a combined clinical end point at 1 year (death, MI, class III-IV angina, and repeat revascularization) of 9.4% to 13.8% in patients with and without graft failure on follow-up angiography.[14] The trial from the Randomized On/Off Bypass (ROOBY) investigators comparing the radial artery and the saphenous vein graft reported a cumulative incidence of MI, cardiac mortality, or repeat revascularization of 11.6%, whereas the Arterial Revascularization Trial comparing single with bilateral internal thoracic artery use reported a 1-year cumulative incidence of 4.7%.[15,16] This low event rate in the ART trial may be underestimated because the follow-up was based on "patient reported outcomes"—telephone and questionnaire follow-up without a standardized definition of MI.

In this trial, the overall LITA-LAD 6-month patency rate on angiographic follow-up was 92.5%, with a patency of 97.5% in the Mx-catheter group. These results are similar to patency rates of 91% to 98% in other CABG trials performing angiographic follow-up at 1 year.[12,13,15,17] For this trial, patency was performed at 6 months instead of 1 year, as based on the advised follow-up of (comparable) bare metal stents in the European guidelines on medical devices (2008). Reported C-port device patency rates varied from 83.7% to 99%.[10,11,18] Notably, improvements in laser catheter design during the trial were associated with clinically relevant higher patency rates in the second half of the trial using the Mx-catheter which is the catheter type that will be used in future trials. However, this did not reach significance ($P = .079$) and possibly is associated with surgeon learning curve as well. In

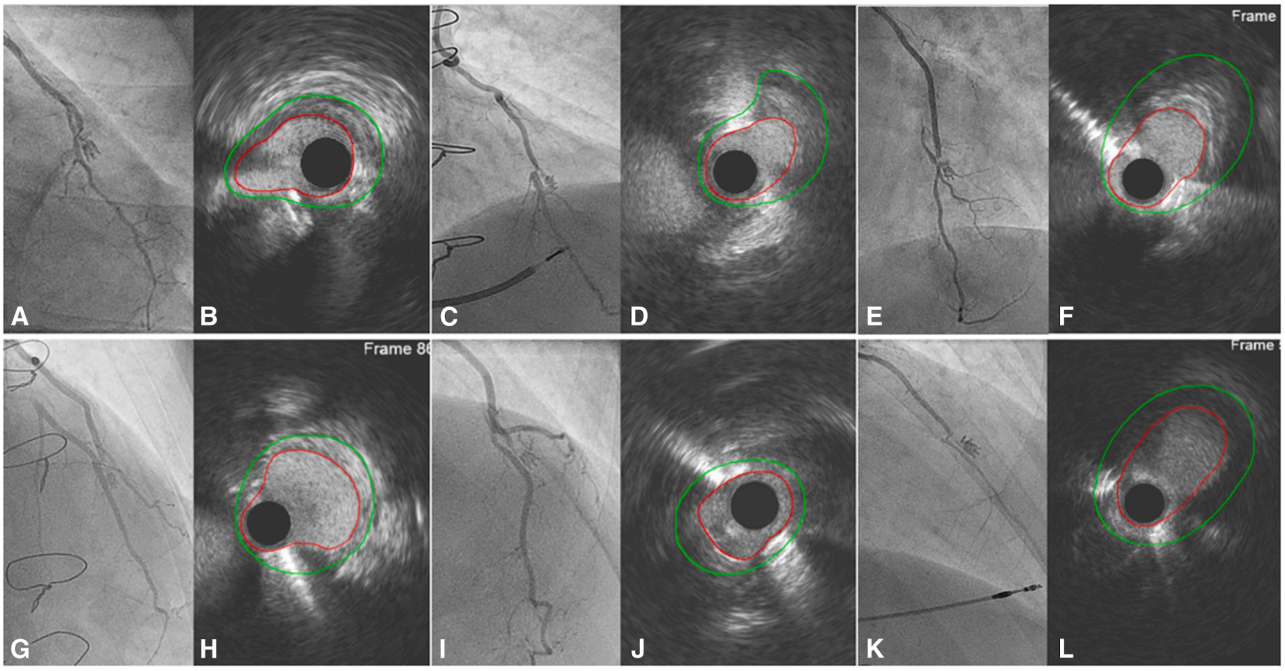

FIGURE 5. Coronary angiography (*CAG*) assessed as FitzGibbon B and corresponding intravascular ultrasound (*IVUS*) results of the left internal thoracic artery to left anterior descending coronary artery anastomosis in 6 individual patients. The *green line* depicts the vessel, and the *red line* is the measured lumen. A, CAG of patient 1. B, IVUS of patient 1. C, CAG of patient 2. D, IVUS of patient 2. E, CAG of patient 3. F, IVUS of patient 3. G, CAG of patient 4. H, IVUS of patient 4. I, CAG of patient 5. J, IVUS of patient 5. K, CAG of patient 6. L, IVUS of patient 6.

contrast to the satisfying MACE rates in this trial, angiographic analysis revealed an FG B classification of 51.6%. Patients with a visually significant stenosis on CAG were discussed in the Heart Team. Artefacts caused the bare metal clip—potentially due to x-ray attenuation, scattering, or image postprocessing—may explain angiographic appearances that led to FG B ratings. This effect was not observed in photon-counting CT scans in the 3 patients refusing CAG. Interestingly, the high proportion of FG B findings is a point of concern that is not reflected by clinically related findings at 1-year follow-up. Furthermore, IVUS imaging in 6 patients did not show any reduction of anastomotic surface area (Figure 5, Table E2). We therefore speculate that the angiographic findings might have overestimated the degree of stenosis. Longer-term follow-up studies are necessary to clarify this.

Histologic results from preclinical porcine models similarly showed an increase in anastomotic orifice area at 6 months compared with directly postoperative.[6] Remodeling of the ELANA anastomoses is possible as the anastomotic opening of the clip is 4.77 mm^2, whilst the laser only excises a flap of 3.34 mm^2. Comparable positive remodelling of the LITA has also been observed in sutured anastomoses at 1-year angiographic term follow-up.[19]

The future intended purpose of this anastomotic device is to enable formation of a safe and standardized anastomosis, possibly in minimally invasive CABG approaches, such as totally endoscopic coronary artery bypass, which remains technically challenging and is therefore performed only in a few centers worldwide.[20] Unlike earlier sutureless devices, the ELANA system facilitates off-pump surgery without interruption of the coronary blood flow and does not require a preexisting arteriotomy. Only 2 critical steps are performed on the target vessel: introduction of the 2 pins of the system into the vessel and the laser-guided excision of the tissue flap out of the anterior wall. As such, the ELANA system has the potential to make less-invasive CABG more reproducible and widely applicable.

The study has several limitations. First, since only 2 surgeons performed all the procedures, the usability of the ELANA system has to be further explored. Second, although the results are encouraging, the follow-up is limited to 1 year so far; longer follow-up is ongoing. Third, although the 2 surgeons were trained extensively, the results could be biased by a learning curve effect.

CONCLUSIONS

This trial demonstrated the safety and effectiveness of the ELANA anastomotic device in CABG, but long-term follow-up is needed to confirm this. Future trials are needed to investigate whether this device facilitates less and minimally invasive approaches in CABG.

Conflict of Interest Statement

B. van Putte, P. Klein, and S. Jacobs are consultants for AMT Medical. L. Moormans and G. Bronkers are technical employees of AMT Medical. All other authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

Data Availability

Anonymous participant data are available on reasonable request. Requests will be reviewed by the principle investigator and the sponsor. The sponsor had no involvement in patient inclusion, data collection, or outcome assessment to minimize the risk of bias.

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Key Words: coronary artery bypass graft, anastomotic device, off-pump CABG, myocardial revascularization

TABLE E1. Definitions of MACE components

MACE component	Definition
Cardiac mortality	All mortality within the first 30 days is considered cardiac unless a specific noncardiovascular cause is evident and considered to be the cause of death (eg, malignancy)
Myocardial infarction	Acute myocardial injury with clinical evidence of acute myocardial ischemia and with detection of a rise and/or fall of cardiac troponin values within at least 1 value above the 99th percentile of the upper reference limit and at least 1 of the following: • Symptoms of myocardial ischemia • New ischemic ECG changes • Development of pathologic Q waves • Imaging evidence of new loss of viable myocardium or regional wall motion abnormality in a patters consistent with an ischemic aetiology • Identification of a coronary thrombus by angiography, including intracoronary imaging or by autopsy
Repeated clinically driven target-vessel coronary revascularization	New CABG procedure or PCI of the ELANA target vessel based on clinically indicated angiography, documenting new graft or native target vessel occlusion

MACE, Major adverse cardiac event; *ECG*, electrocardiographic; *CABG*, coronary artery bypass grafting; *PCI*, percutaneous coronary intervention; *ELANA*, excimer laser-assisted nonocclusive anastomosis.

TABLE E2. Minimal lumen area (MLA) measured using intravascular ultrasound (IVUS), compared with the lumen area created by the excimer laser

Patient	IVUS MLA, mm^2	Anastomotic opening created by laser, mm^2	Delta, mm^2 (%)
1	2.78	3.34	−0.56 (−16.8%)
2	2.78	3.34	−0.56 (−16.8%)
3	3.75	3.34	+0.41 (+12.3%)
4	4.60	3.34	+1.26 (+37.7%)
5	2.55	3.34	−0.79 (−23.7%)
6	5.23	3.34	+1.89 (+56.6%)
Average	3.62	3.34	+0.28 (+8.4%)