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Stenting or Surgery for De Novo Common Femoral Artery Stenosis

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CME/MOC Objective for This Article: At the end of the activity the reader should be able to: 1) appraise the rate of major adverse cardiovascular and local complications in patients undergoing surgical repair of the common femoral artery stenosis; 2) compare the rates of perioperative mortality and morbidity, morphological and hemodynamic outcomes in patients undergoing stenting or surgical repair for de novo common femoral artery stenosis; and 3) recognize the limitations of balloon angioplasty and bioresorbable scaffold deployment in attempting to obtain revascularization for common femoral artery stenosis.

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Stenting or Surgery for De Novo Common Femoral Artery Stenosis

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ABSTRACT

OBJECTIVES The TECCO (Traitement des Lésions Athéromateuses de l'Artère Fémorale Commune par Technique Endovasculaire Versus Chirurgie Ouverte [Endovascular Versus Open Repair of the Common Femoral Artery]) trial is a randomized comparison of safety and efficacy of stenting versus open surgery for de novo common femoral artery (CFA) stenosis.

BACKGROUND Surgery for CFA lesions is considered effective and durable. Despite the widespread use of endovascular repair for infrainguinal disease, the value of this procedure for such lesions is uncertain.

METHODS From February 23, 2011, to September 5, 2013, a total of 117 patients with de novo atherosclerotic lesions of the CFA were randomly assigned to undergo surgery (n = 61) or stenting (n = 56). The main exclusion criteria were asymptomatic disease, restenosis, and thrombosis of the CFA. The primary outcome was the morbidity and mortality rate within 30 days. This includes any general complications or local complications that caused or prolonged hospitalization and/or re-intervention, lymphorrhea of more than 3 days, and post-operative paresthesia that required drugs. The median duration of follow-up was 2 years (interquartile range [IQR]: 19.8 to 24.9 years).

RESULTS Primary outcome events occurred in 16 of 61 patients (26%) in the surgery group and 7 of 56 patients (12.5%) in the stenting group (odds ratio: 2.5; 95% confidence interval: 0.9 to 6.6; $p = 0.05$). The mean duration of hospitalization was significantly lower in the stenting group (3.2 ± 2.9 days vs. 6.3 ± 3 days; $p < 0.0001$). At 24 months, the sustained clinical improvement, the primary patency rate, and the target lesion and extremity revascularization rates were not different in the 2 groups.

CONCLUSIONS In patients with de novo atherosclerotic lesions of the CFA, the perioperative morbidity and mortality rate was significantly lower among patients who underwent endovascular therapy by stenting compared with surgery, whereas clinical, morphological, and hemodynamic outcomes were comparable at mid-term. (Traitement des Lésions Athéromateuses de l'Artère Fémorale Commune par Technique Endovasculaire Versus Chirurgie Ouverte [Endovascular Versus Open Repair of the Common Femoral Artery] [TECCO]; NCT01353651) (J Am Coll Cardiol Intv 2017;10:1344–54)

Despite the widespread use of endovascular repair for infrainguinal disease, surgery is still considered the gold standard treatment for common femoral artery (CFA) atherosclerotic lesions because of its safety and its durability (1,2). Furthermore, endovascular repair for CFA disease, and particularly stent use, could compromise future femoral surgical approaches, increase the risk of potential future surgical CFA interventions, and be associated with stent fracture due to the mobility of the hip joint (2). However, the level of evidence for surgery as the standard for CFA treatment is weak (Level 4, Grade C) (2). Indeed, CFA surgery is poorly evaluated. Only a few prospective or retrospective registries have been reported (1,3–8). Moreover, in a recent large registry from the National Surgical Quality Improvement Program database, the authors stated that surgery was not as "benign" as believed (6).

Therefore, endovascular repair for the CFA should be regarded as an option. So far, conventional balloon angioplasty or bioabsorbable stents have failed to show promising results (9–11). Recent publications have provided data in favor of CFA stainless-steel stenting (9,10,12). In a pilot study, we reported that stenting of CFA lesions seemed to be a safe technique with acceptable clinical outcomes long term (13,14).

ABBREVIATIONS AND ACRONYMS

CFA = common femoral artery

CI = confidence interval

HR = hazard ratio

So far, no randomized study has compared surgery to stainless-steel stenting. In the current trial, the TECCO (Traitement des Lésions Athéromateuses de l'Artère Fémorale Commune par Technique Endovasculaire Versus Chirurgie Ouverte [Endovascular Versus Open Repair of the Common Femoral Artery]) trial, we compared surgery versus stainless-steel stenting in patients with CFA de novo atherosclerotic lesions.

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METHODS

TRIAL DESIGN. The TECCO trial was a French multicenter, prospective, randomized controlled trial that was conducted at 17 centers of vascular and endovascular surgery. Eligible patients were randomly assigned in a 1:1 ratio to surgery or stenting. Simple randomization was performed with the use of a web-based system. Randomization was stratified according to investigational site to ensure proportional assignment. Because of the nature of the interventions, patients and treating physicians were aware of study-group assignments. All trial surgeons were senior consultants and routinely performed endovascular and open surgery for infrainguinal disease. This trial is registered with ClinicalTrials.gov (NCT01353651). The full protocol is available online.

PATIENTS. Detailed inclusion and exclusion criteria are provided in detail in the full protocol, available online. Briefly, patients were eligible for enrollment if they presented with de novo atheromatous CFA stenosis, symptomatic (Rutherford stages 3 to 6), and a hemodynamically significant lesion. Main exclusion criteria were patients with CFA thrombosis, restenosis, and nonatheromatous lesions (dysplasia, posttraumatic, inflammatory). Common femoral occlusive lesions were classified according to a classification described previously (13). CFA lesions were classified into 4 types: in type I, lesions were located at the iliac external artery and were extended to the CFA; in type II, lesions were limited to the CFA; in type III, lesions were located at the CFA and its bifurcation; and type IV represents a restenosis bypass anastomosis and was excluded from this study.

TREATMENTS. In both groups, the type of anesthesia to use was left to the choice of the physicians, and all patients received intraoperatively 50 IU/kg of unfractionated heparin.

Surgery procedure. Surgery was performed according to the operator's routine technique, such as endarterectomy of the CFA with or without patch or bypass (prosthetic/venous).

Stenting procedure. In the stenting group, access to the culprit lesion was achieved either by way of an over-the-aortic bifurcation or via a brachial approach with the use of a dedicated 6-F or 7-F long sheath. After sheath placement, a biplane angiogram was performed in an ipsilateral anterior oblique projection to visualize the CFA and its bifurcation. After successful guidewire passage of the target lesions, catheterization of the deep femoral artery was preferably performed to secure the deep femoral artery during the procedure.

The last generation of self-expandable stents was recommended to treat type 1 and type 2 lesions. In these cases, primary self-expandable stenting without lesion pre-dilatation was realized. In tight stenosis that precluded stent advancement, angioplasty with a 3-mm to 4-mm balloon was done to allow stent placement. Self-expandable stent post-dilatation was mandatory in case of inadequate deployment. Self-expandable stent post-dilatation was realized such that the balloon nominal diameter was inferior to the stent diameter by 1 mm to reduce medial damage (15). In type III lesions, in case of lesions that involved the common femoral bifurcation, balloon-expandable stents were used to treat ostial stenoses of superficial and deep femoral arteries. In type III lesions, in case of occlusion of the superficial femoral artery, the superficial femoral artery was abandoned and a self-expandable stent was placed from the CFA into the deep femoral artery. In all cases, the technical result of the procedure was assessed by biplane angiogram.

In both groups, the decision to conduct concomitant endovascular procedures, as well as medical treatment, was left at the discretion of the treating physician, but the choices were recorded.

STUDY OVERSIGHT. The TECCO trial was conducted in accordance with the ICH-E6, French Good Clinical Practice guidelines, and appropriate regulatory requirements. The ethical committee approved the study for France (dossier #2010-R37). All patients provided written informed consent. A safety monitoring committee oversaw the safety of the trial. The trial was designed by the first author (Y.G.) in collaboration with all investigators. Data were gathered and analyzed by the investigators. The initial draft of the paper was written by the first and last authors (Y.G. and B.N.) with the help of a professional medical writer. All authors assume responsibility for the completeness and accuracy of the data and the analyses, for the adherence of the trial to the

protocol and making the decision to submit the manuscript for publication. This study was supported by a grant from the French ministry of health (PHRC 2010 - DGOS 20-03).

ASSESSMENTS. The primary outcome was the perioperative morbidity and mortality rate, which was assessed within 30 days after the procedure. This comprised any general complications or local complications that caused or prolonged hospitalization and/or re-intervention, lymphorrhea of more than 3 days, and post-operative paresthesia that required drugs. The general complications included death from any cause, major adverse clinical events, and major amputations (transfemoral and transtibial). Major adverse events included stroke, myocardial infarction, procedural-related serious adverse events and device failure or malfunction. Stroke was defined as a sudden, focal neurological deficit resulting from a cerebrovascular cause, resulting in death or lasting longer than 24 h. Myocardial infarction was defined as presumed ischemic symptoms (chest pain, new ST-segment elevation of >1 mm in 2 or more contiguous leads, and troponin level higher than 2 times the upper limit of the normal). Local complications were hematoma, active bleeding, local infection, thrombosis, delayed wound healing, false aneurysm, and arteriovenous fistula. Delayed wound healing was defined as absence of scarring at the 30-day follow-up visit. The pre-specified secondary outcomes included technical success, length of hospital stay, primary and secondary sustained clinical improvement, the rate of death from any cause, primary patency, target lesion revascularization, target extremity revascularization, resting ankle-brachial index, and stent fracture rate. The secondary endpoints were assessed at 1, 6, 12, and 24 months, except the stent fracture rate, which was assessed at 6, 12, and 24 months.

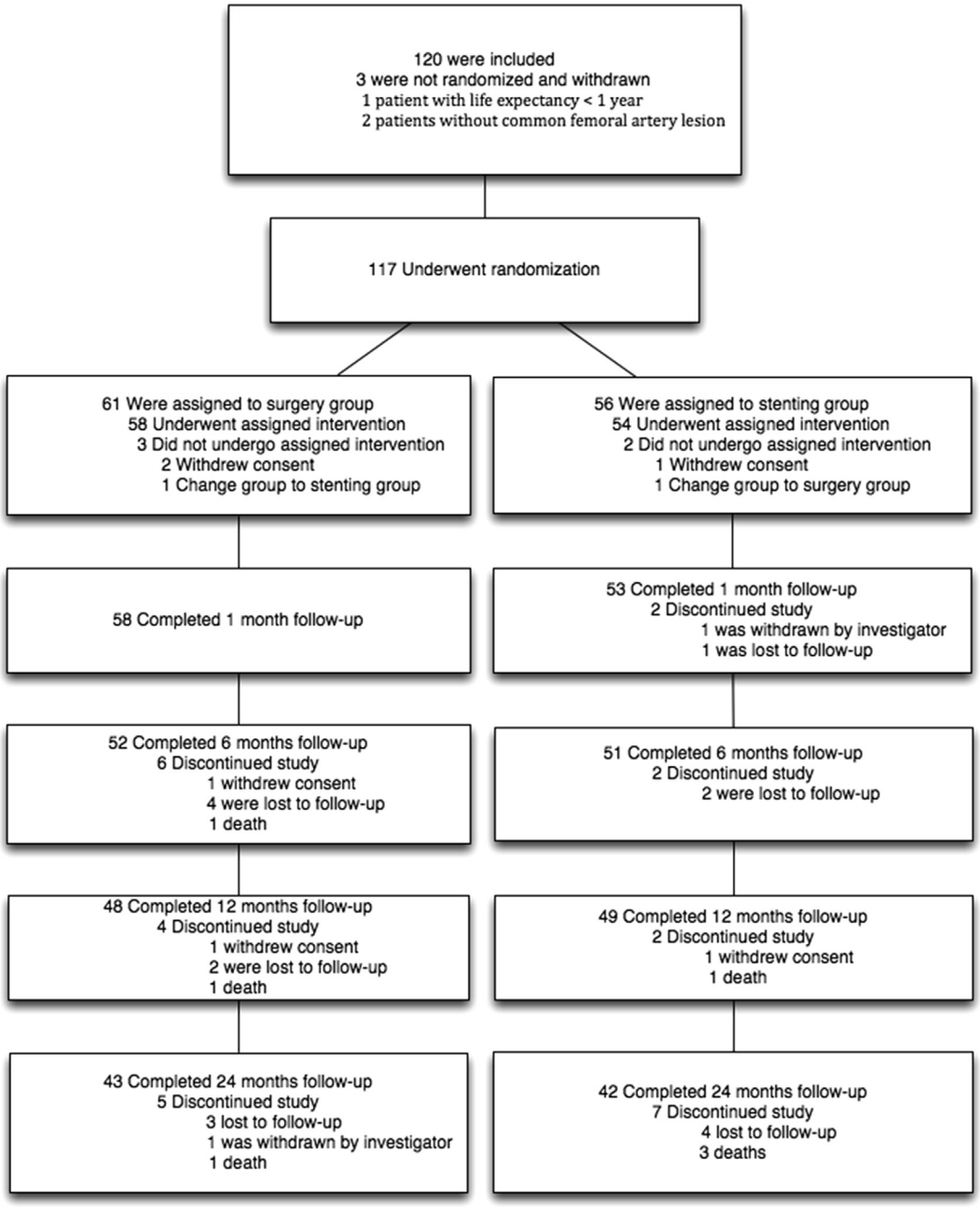
Primary sustained clinical improvement was defined as a sustained upward shift of 1 category of the Rutherford classification for patients with claudication, and by wound healing and rest pain resolution for patients in critical limb ischemia, without the need for repeated target lesion revascularization in surviving patients (16). Secondary sustained clinical improvement was defined as primary sustained clinical improvement including the need for repeated target lesion revascularization (16). Primary patency rate was defined as the lack of restenosis, without the need for reintervention of the target lesion during follow-up. Restenosis was defined as a reduction in the luminal diameter of more than 50%, and by a peak systolic velocity index ≥2.4 at the target lesion, as determined by duplex ultrasound (17). Target lesion revascularization expresses the frequency of the need for repeated procedures (endovascular or surgical) due to a problem arising from the lesion initially treated in surviving patients with preserved limbs (16). Target extremity revascularization expresses the frequency of the need for repeated procedures (endovascular or surgical) due to a problem arising remote from the lesion initially treated in surviving patients with preserved limbs (16). Procedural success was defined by the ability to cross the lesion with the guidewire and to inflate the artery with a stent in the endovascular group, and by the completion of the procedure without intraoperative thrombosis in the surgery group. The resting ankle-brachial index was defined as the ratio of the blood pressure at the ankle to the blood pressure in the upper arm. The occurrence of stent fracture was determined by biplane radiography. Stent fractures were classified according to the Jaff et al. (18) classification.

SURVEILLANCE PROTOCOL. Follow-up visits were scheduled to take place at 30 days, 6 months, 12 months, and 24 months. Patients were defined as lost to follow-up when no further follow-up studies were available beyond a particular completed follow-up interval. The examination included clinical, morphological, and hemodynamic assessments such as staging of peripheral artery disease according to the Rutherford classification, duplex scan, and measurement of the ankle-brachial index (19). Computed tomography angiography was indicated in case of clinically deteriorating symptoms and/or when the findings in the duplex scan suggested that restenosis had developed. Biplane x-rays were realized at 6, 12, and 24 months for evaluation of stent fractures.

STATISTICAL ANALYSIS. We calculated that a sample of 120 patients, randomly assigned in a 1:1 ratio, would be required to provide the study with an 80% power to detect a between-group difference of 20 percentage points in the morbidity and mortality rates (25% in the surgery group and 5% in the stenting group), at a 2-sided alpha level of 0.05. These estimates were based on our pilot study for the stenting group and on the published reports for surgery (13). Continuous data are presented as the mean ± SD or, for non-normal distributions or censored datasets, as median with interquartile range. Categorical data are given as count and percentage. Continuous data were compared with the use of the Student *t* test; the chi-square test or Fisher exact test were used for comparison of categorical data.

A modified intention-to-treat analysis on the primary endpoint was performed to include only

FIGURE 1 Randomization and Follow-Up



patients who had undergone randomization and met the major inclusion criteria. The per-protocol analysis included all patients who completed the study without any major protocol violations. All patients are analyzed in their initial study group assignment. Logistic regression was performed to assess the association between group and morbidity/mortality, and to adjust for potential confounding. No random effect on center was used because the center variance component was small enough to be ignored. The Kaplan-Meier method was used to evaluate time-to-event data for global survival, target lesion revascularization, target extremity revascularization, and sustained clinical improvement over the 24-month

follow-up period. The differences between the groups were assessed using the log-rank test, and a hazard ratio (HR) with a confidence interval (CI) at 95% in the Cox model. Mixed models were used to analyze evolution of the ankle-brachial index over time. All p values are 2-sided; $p < 0.05$ indicated a statistically significant difference, and no correction was made for multiple comparisons. All statistical analyzes were performed using SAS version 9.4 (SAS Institute, Cary, North Carolina).

RESULTS

STUDY POPULATION. From February 23, 2011, to September 5, 2013, we enrolled 120 patients (Figure 1). Of these, 3 patients were not randomized and were withdrawn from the analysis. In 1 of these cases, the patient's life expectancy was considered to be <1 year, and in the 2 other cases, further morphological examinations did not show any CFA lesions. Consequently, these 3 patients were not treated and not followed-up. Sixty-one patients were randomly assigned to undergo surgery, and 56 patients, to receive endovascular repair. The characteristics of the patients in the intention-to-treat population were well balanced between both study groups (Table 1). The median follow-up was 24 months (interquartile range [IQR]: 19.8 to 24.9 months). Follow-up was completed for 112 patients at 30 days after the procedure and for 86 patients at 2 years (73.5%). Among the 31 patients who could not be evaluated at 2-years, 9 withdrew consent for further follow-up, and 16 were lost to follow-up by site investigators.

PROCEDURES. Procedural characteristics and target lesions at baseline are described in Table 2. Procedural success rates were 100% and 94.6% in the surgery and stenting groups, respectively. Three patients in the stenting group required intraoperative conversion to surgery. A majority of type 3 lesions were treated in both groups (Table 1). There was no difference in CFA lesion types between the open-surgery and the stenting groups ($p = 0.33$). In the stenting group, among type 3 lesions, 15 cases were stented into the CFA and deep femoral artery, 8 cases were stented into the CFA and superficial femoral artery, and 10 cases were stented into the superficial femoral artery and the deep femoral artery. Nine patients had general anesthesia in the stenting group. Among them, 1 patient had a major amputation despite a patent CFA stenting. Another patient had an intraoperative complication due to the approach that required an open repair. In the remaining cases, general anesthesia was needed in patients who were restless and in pain. No significant difference was observed regarding the rate of concomitant endovascular repair among both groups (surgery 26 of 58; stenting 17 of 54; $p = 0.67$). Details regarding concomitant procedures are given in Table 2.

TABLE 1 Characteristics of the Patients

	Surgery (n = 61)	Stenting (n = 56)	p Value
Age, yrs	68 ± 8	68 ± 9	0.93
Male	51 (84)	48 (86)	0.75
Hypertension	44 (72)	45 (80)	0.30
Hyperlipidemia	40 (66)	37 (66)	0.96
Diabetes mellitus	25 (41)	17 (31)	0.23
Smoking at baseline	28 (46)	26 (46)	0.95
Coronary artery disease	28 (46)	27 (48)	0.81
Renal insufficiency	8 (13)	6 (11)	0.69
On dialysis	1 (13)	1 (17)	–
Obesity (BMI >25 kg/m^2)	39 (64)	31 (58)	0.55
Statin treatment	50 (82)	38 (68)	0.08
Antiplatelet drug	57 (93)	50 (89)	0.32
ACE inhibitor	19 (31)	22 (39)	0.23
Rutherford stage of PAD			0.23
2	2 (3)	1 (2)	
3	54 (89)	44 (80)	
4	5 (8)	7 (13)	
5	0 (0)	3 (5)	
Type of lesion			0.33
I	6 (10)	9 (16)	
II	21 (34)	13 (23)	
III	34 (56)	34 (61)	
Degree of stenosis			0.17
70% to 90%	43 (70)	35 (63)	
≥90%	14 (23)	20 (36)	
TASC II for femoropopliteal disease			0.76
A	11 (18)	10 (18)	
B	13 (21)	12 (21)	
C	6 (10)	10 (18)	
D	11 (18)	9 (16)	
Runoff vessels, n			0.98
0	2 (3)	2 (4)	
1	5 (9)	6 (11)	
2	15 (25)	14 (25)	
3	37 (63)	33 (60)	

Values are mean ± SD or n (%). Rutherford stage 2 corresponds to moderate intermittent claudication, stage 3 to severe intermittent claudication, stage 4 to ischemic pain while the patient is resting, and stage 5 to ischemic ulcers.

ACE = angiotensin-converting-enzyme; BMI = body mass index; PAD = peripheral artery disease; TASC = Trans-Atlantic Inter-Society Consensus document II.

OUTCOMES. Within 30 days, primary outcome events occurred in 16 of 61 patients (26%) in the surgery group and in 7 of 56 patients (12.5%) in the stenting group (Table 3). The rate of primary outcome events was therefore significantly lower in the

TABLE 2 Baseline Angiographic and Interventional Data

	Surgery (n = 58)	Stenting (n = 54)	p Value
Type of anesthesia			<0.001
Local	1 (2)	41 (75)	
Loco-regional	11 (19)	4 (7)	
General	46 (78)	9 (16)	
Surgery technique			
Endarterectomy	46 (69)	NA	
With venous patch	7 (12)	NA	
With prosthetic patch	37 (64)	NA	
Direct suture	2 (3)	NA	
Bypass with a prosthesis	11 (19)	NA	
Eversion	1 (2)	NA	
Crossover access	NA	43 (78)	
Brachial access	NA	7 (13)	
Femoral ipsilateral	NA	4 (7)	
Self-expandable stents	NA	48 (67.5)	
Mean diameter, mm	NA	7 ± 1	
Mean length, mm	NA	41 ± 17	
Balloon-expandable stents	NA	23 (32.5)	
Mean diameter, mm	NA	6 ± 1	
Mean length, mm	NA	25 ± 11	
Duration of the procedure, min	NA	82 ± 53	
Amount of contrast agent, ml	NA	70 ± 53	
Pre-dilatation realized	NA	34 (62)	
Arterial closure devices used	NA	15 (27)	
Concomitant endovascular procedures			0.67
None	33 (57)	37 (68)	
Inflow	13 (22)	8 (15)	
Outflow	11 (19)	8 (15)	
In- and outflow	1 (2)	1 (2)	

Values are n (%) or mean ± SD. TASC range from A to D for femoropopliteal disease, with higher classes indicating more complex lesions.

NA = not applicable; TASC = Trans-Atlantic Inter-Society Consensus document II.

stenting group (odds ratio: 2.5; 95% CI: 0.9 to 6.6; p = 0.05). In addition, we also observed a significantly lower rate of primary outcome events in the stenting group according to the 105 patients in the per protocol analysis (6% vs. 26%; odds ratio: 4.5; 95% CI: 1.7 to 12.0; p = 0.005). During the perioperative period, no death was observed in either group, but 1 stroke occurred 30 days after the procedure in the stenting group. The difference in primary outcome events between the 2 groups was driven by a trend toward an increase in local complications in the surgery group, especially delayed wound healing. The mean length of hospital stays was 3.2 ± 2.9 days for patients in the stenting group and 6.3 ± 3.0 days for the surgery group (p < 0.001).

During the trial, 3 patients died of cancer, 2 of cardiovascular diseases, and 1 due to sepsis secondary to a chronic arterial wound in the contralateral foot. For 1 patient, the cause of death was unknown. At 2 years, the primary sustained clinical improvement rate in the surgery and the stenting groups were 76.1 ± 6.6 and 74.8 ± 6.5, respectively (odds ratio: 1.1; 95% CI: 0.5 to 2.5; p = 0.82). The Rutherford category assessment was significantly improved at 2 years compared with baseline in both groups (p < 0.0001) without any difference between the groups at 2 years (p = 0.89) (Figure 2). No difference was seen between the 2 groups in terms of survival, target lesion revascularization, target extremity revascularization, and primary patency (Figure 3). Comparison of the open-surgery and stenting groups according to the inflow and/or the outflow concomitant endovascular treatment did not yield any significant differences in terms of mortality (HR: 1.3; 95% CI: 0.3 to 5.7; p = 0.77), target lesion revascularization (HR: 0.99; 95% CI: 0.35 to 2.86; p = 0.99), target extremity revascularization (HR: 1.3; 95% CI: 0.5 to 3.1; p = 0.60), and primary patency (HR: 0.79; 95% CI: 0.25 to 2.50; p = 0.68). The resting ankle-brachial index was significantly improved at 2 years compared with baseline in both groups without any difference between the groups at 2 years (Figure 4). Among the stenting group, 1 stent fracture was observed at 24 months. The fracture was a type 3. Despite the stent fracture, no restenosis was observed, and no reintervention was required.

DISCUSSION

CFA atherosclerotic lesions currently remain one of the last limitations for the adoption of endovascular repair as the first-line treatment for infrainguinal atherosclerotic disease. In our trial, we observed that stenting in such patients reduced perioperative morbidity and mortality, and was associated with a similar 2-year outcome compared with surgery. This benefit in primary outcome was driven by the reduction in the rate of local complications.

The primary advantage for endovascular repair over surgery is procedural mortality and morbidity (20). Our results show a significantly higher morbidity and mortality rate in the surgery group compared with the stenting group. Despite most surgeons considering common femoral open repair as a safe treatment, trials have reported elevated complications rates. In a large registry, Nguyen et al. (6) reported a morbidity and mortality rate of 15%, including a 3.4% death rate. In a randomized study comparing surgery versus bioabsorbable stents, Linni et al. (11) observed a rate of surgical site infections of 18%. Paresthesia as a post-operative complication of the CFA approach is poorly reported in the published reports. As we showed, it is a frequent complication

that required analgesic agents in 6% of the treated patients. The endovascular repair group was not exempt from complications. In particular, we noted 1 patient with a stroke. In this case, the occurrence of the stroke was probably not related to the procedure because it was observed 30 days after the intervention. An analysis of the published reports regarding CFA endovascular repair suggests that morbidity and mortality rates are consistent with our per protocol analysis, ranging from 5% to 7.2% (10,13,21). We noted also a significant decrease in the length of hospitalization stay in favor of the stenting group, despite 2 overnight's stay for peripheral arterial disease endovascular procedures being the standard of care. In France, this trend could be reinforced with the development of same-day discharge management. Indeed, several studies have shown that endovascular repair could be performed safely by ambulatory management (22,23). It is interesting to note that a majority of type 3 lesions were treated in both groups. CFA type 3 lesions involve the CFA bifurcation and make the endovascular treatment more challenging. Bonvini et al. (10) already reported that procedures involving the common femoral bifurcation were associated with an increase in the risk of procedural failure and a trend toward more restenosis and target lesion revascularization at 1 year. In the surgery group, endarterectomy with prosthetic patch was the most common technique used to treat CFA stenosis. This observation was in line with the published reports where endarterectomy with patch appears to be the most frequently performed procedure to treat such lesions (1,3,6,8,24). But, according to the protocol, the choice of the technique for the surgery group was left to the discretion of the physician because no data have shown the superiority of one technique over another.

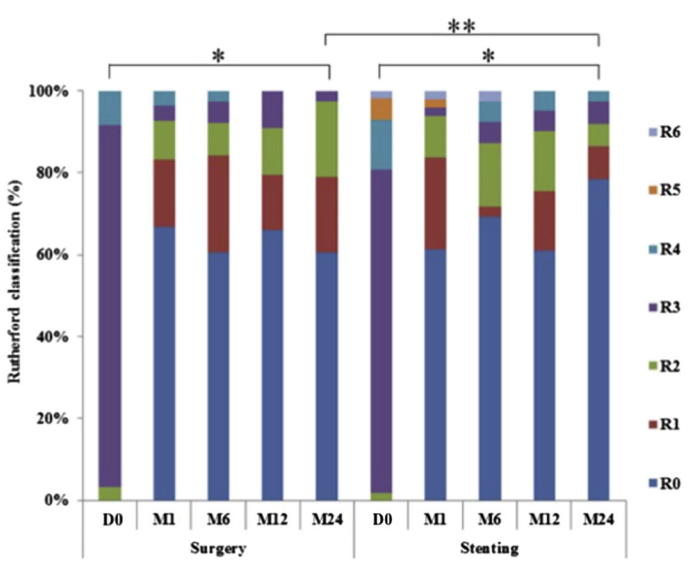
So far, conventional balloon angioplasty or bioabsorbable stents have failed to show promising results (9–11). For Bonvini et al. (10), the use of stents was identified as the only independent protective factor against procedural failure, target lesion revascularization, and 1-year restenosis. For Baumann et al. (9), primary sustained clinical improvement was significantly better in patients who had stents implanted. In a randomized trial comparing bioabsorbable stenting versus surgery, Linni et al. (11) concluded that bioresorbable stenting was not an option for occlusion and a limited option for common femoral stenosis. Bioabsorbable stents have already shown a lack of radial force, particularly in calcified vessels (25). Interestingly, we have previously reported that osteoid metaplasia, a mature bone structure, was present in the majority of de novo CFA lesions (26,27). The presence of this solid and rigid structure in the CFA could jeopardize the success of endovascular procedures and necessitate better scaffolding in the form of a stainless-steel stent.

TABLE 3 Primary Outcome and Components of the Primary Endpoint, According to Treatment Group*

	Intent-to-Treat Analysis			Per Protocol Analysis		
	Surgery (n = 61)	Stenting† (n = 56)	p Value	Surgery (n = 58)	Stenting (n = 47)	p Value
General complications						
Death	0 (0)	0 (0)		0 (0)	0 (0)	
Stroke	0 (0)	1 (1.8)		0 (0)	1 (2.1)	
Myocardial infarction	0 (0)	0 (0)		0 (0)	0 (0)	
Major amputation	0 (0)	0 (0)		0 (0)	0 (0)	
Local complications						
Hematoma	3 (5)	0 (0)		3 (5)	0 (0)	
Thrombosis	0 (0)	1 (1.8)		0 (0)	1 (2.1)	
Lymphorrhea	2 (3.2)	0 (0)		2 (3.4)	0 (0)	
Delayed wound healing	10 (16.4)	0 (0)		10 (17.2)	0 (0)	
False aneurysm	0 (0)	0 (0)		0 (0)	0 (0)	
Arteriovenous fistula	0 (0)	0 (0)		0 (0)	0 (0)	
Paresthesia	4 (6.5)	0 (0)		4 (6.9)	0 (0)	
Local infection	3 (5)	1 (1.8)		3 (5.1)	1 (2.1)	
Vascular perforation	0 (0)	1 (1.8)		0 (0)	1 (2.1)	
Primary endpoint	16 (26)	7 (12.5)†	0.05	16 (26)	3 (6.4)	0.005

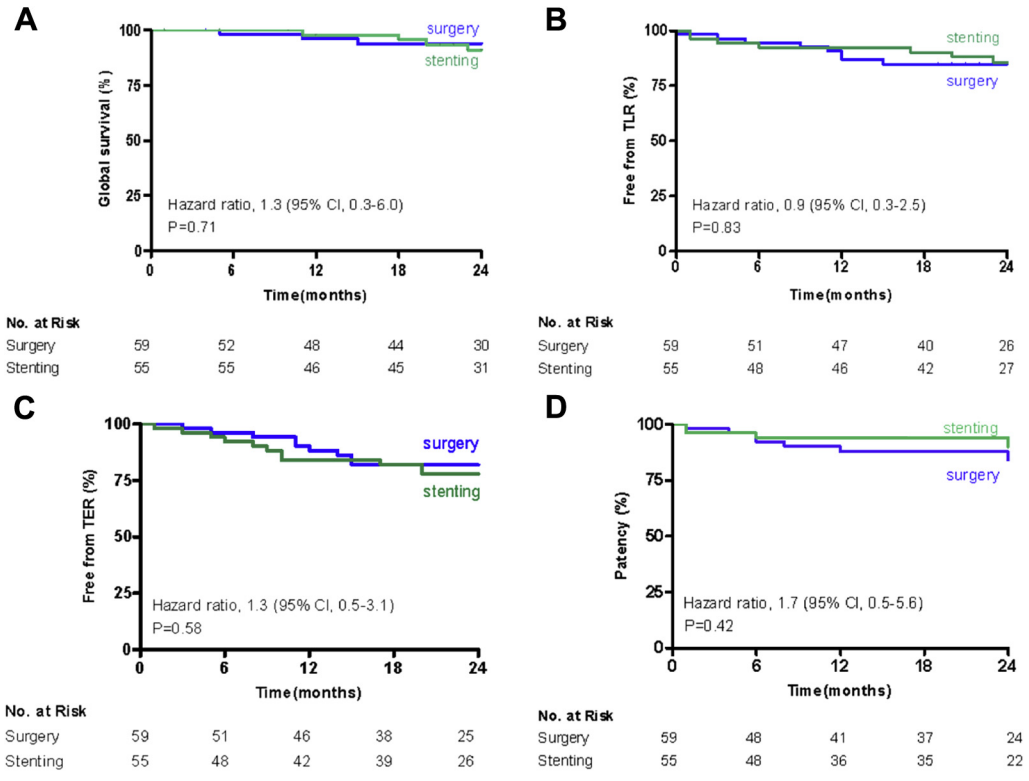
Values are n (%). *Patients may have had more than 1 event. †In the stenting group, 1 patient did not have the stenting procedure, and 2 patients discontinued the study at 1-month follow-up (1 was withdrawn by the investigator and 1 was lost to follow-up). For these 3 patients, we assigned a positive primary endpoint.

FIGURE 2 Rutherford Category Assignments From Baseline to 2 Years



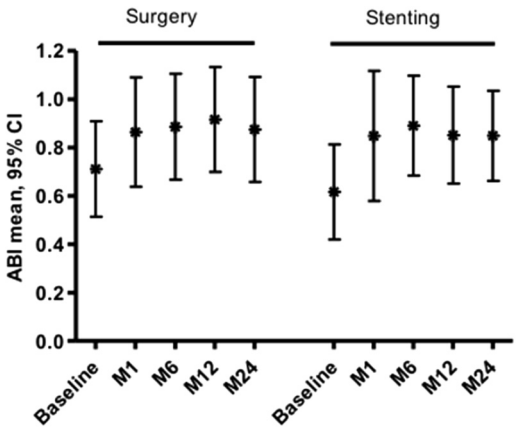
R0 to R6 indicate Rutherford stage 0 to Rutherford stage 6, respectively. D0 indicates the day of the procedure, and M1 through M24 indicate the length of follow-up in months. *$p < 0.0001$; **$p = 0.89$.

FIGURE 3 Kaplan-Meier Estimates



Kaplan-Meier estimates of the rates of death from any cause, freedom from target lesion revascularization, freedom from target extremity revascularization, and primary patency are shown. **(A)** Death from any cause. **(B)** Freedom from target lesion revascularization. **(C)** Freedom from target extremity revascularization. **(D)** Primary patency. CI = confidence interval; TER = target extremity revascularization; TLR = target lesion revascularization.

FIGURE 4 Resting ABI



ABI = ankle brachial index; other abbreviations as in Figures 2 and 3.

Among other endovascular options, debulking devices such as for atherectomy could be proposed to retrieve calcifications (28). So far, no head-to-head comparison has been realized to assess debulking devices for CFA lesions.

Our results show that the decrease in perioperative complications was not counterbalanced by poorer mid-term outcomes in the stenting group. In the published reports, primary patency for surgery ranges from 85% to 100% at 2 years follow-up, which is in line with our results at 2 years (82.3 ± 5.9) (1,3,5,7). Freedom from target lesion reintervention in our TECCO trial (90% at 1 year) is also comparable to results found in the published reports (ranging from 82% to 90% at 1 year). On the other hand, studies investigating primary stenting also showed comparable results to our trial in terms of primary patency and freedom of target lesion revascularization (13,29,30).

Herein, self-expandable stents were chosen for CFA due to the risk of extrinsic compression and to

make possible a redo CFA puncture through the stent mesh. Others have also reported that CFA stenting did not preclude future CFA vascular access (12). Balloon-expandable stents were chosen to treat superficial and deep femoral arteries ostial stenosis to allow a precise ostial positioning and because shorter length stents were available in comparison to self-expandable stents. At last, a kissing stent of the common femoral bifurcation is possible using 2 0.014-inch balloon-expandable stent delivery systems and a 7-F-compatible long sheath. Recently, we showed that the fear of stent fracture and local complications due to hip mobility were no longer relevant at long term (14).

STUDY LIMITATIONS. First, the trial was not blinded. Indeed, even if surgical interventions are frequently more difficult to blind than randomized clinical trials of drugs, some techniques exist to make blinding feasible in surgical studies (31). The second limitation is related to the interpretation of the absence of a difference in secondary outcomes at 2 years between both groups. Because the trial was not powered to assess these secondary endpoints, definitive conclusions could not be drawn from these. Finally, long-term data are not available to compare both techniques.

CONCLUSIONS

In summary, the results of the TECCO trial support a significant benefit of stenting over surgery with respect to the perioperative morbidity and mortality rate among patients with de novo atherosclerotic stenosis of the CFA.

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PERSPECTIVES

WHAT IS KNOWN? Surgery is still considered as the gold standard treatment for CFA atherosclerotic lesions. However, the level of evidence for surgery as the standard for CFA treatment is weak.

WHAT IS NEW? In the first randomized controlled trial comparing surgery to stainless-steel stenting for CFA de novo atherosclerotic lesions, endovascular treatment of CFA appears as an alternative to surgery.

WHAT IS NEXT? Further endovascular options should be assessed for CFA atherosclerotic lesions.

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