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# Outcomes of covered balloon-expandable stent placement in the treatment of atherosclerotic occlusive disease at the aortic bifurcation

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***Outcomes of covered balloon-expandable stent placement in the treatment of atherosclerotic occlusive disease at the aortic bifurcation***

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**ELIE AMANDINE**

*[Données à caractère personnel]*

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## Résumé

**Titre.** Evaluation de la perméabilité des stents en acier couverts dans le traitement des lésions occlusives aorto-iliaques.

**Objectif.** L'objectif était d'évaluer, à moyen et long terme, la perméabilité primaire des stents couverts utilisés en première intention dans le traitement des lésions occlusives aorto-iliaques et de rechercher les facteurs prédictifs de resténose et de thrombose (FPRT).

**Matériels et Méthodes.** De janvier 2004 à décembre 2014, nous avons colligé l'ensemble des patients ayant bénéficié d'une angioplastie ou recanalisation avec pose de stent couvert de type Advanta® V12 (Maquet) au niveau des artères iliaques primitives. Il s'agit d'une série continue, mono centrique et rétrospective. Le suivi était effectué par une consultation chirurgicale avec un doppler à un mois, puis par un doppler annuel effectué par un médecin vasculaire. Le critère de jugement principal était l'absence de ré-intervention chirurgicale ou endovasculaire pour resténose ou thrombose du stent au niveau de l'artère cible. Les caractéristiques de la population, de la lésion et celles liés à l'intervention ont été analysées en multivarié afin d'identifier les FPRT.

**Résultats.** Un total de 151 artères iliaques ont été traitées chez 110 patients (86% d'hommes, 41 kissing stents). L'âge moyen était de 61 ans (39-86). Le taux de succès technique était de 100%. Il n'y a eu aucun décès peropératoire et deux décès postopératoires : un à J13 de choc septique d'origine urinaire et l'autre à J5 d'infarctus du myocarde. La morbidité locale était faible. La durée de suivi moyenne était de 51,3 mois (0-120). Les taux de perméabilité primaire à 1, 2, 5 et 6 ans étaient respectivement de: 94,2%, 92,1%, 90,4% et 87,3%. Huit thromboses (7,3%) étaient observées dans un délai moyen de 31 mois (0 ; 118) et dix resténoses (9,1%) dans un délai de 47 mois [3 ; 95]. Parmi les 11 patients (10%) réopérés, étaient réalisés: 4 angioplasties itératives et 7 revascularisations par pontage. Seul le sexe féminin a été identifié comme facteur prédictif de thrombose et/ou de resténose de manière significative.

**Conclusion.** Dans notre expérience le traitement endovasculaire par stent couvert des lésions occlusives aorto-iliaques est une technique fiable, efficace et durable. La morbi-mortalité est faible. Dans la littérature, la perméabilité primaire à long terme des stents non couverts ne dépasse pas 80% à un an et 60% à 5 ans.

Absence de conflit d'intérêt.

## Abstract

**Title:** Outcomes of covered balloon-expandable stent placement in the treatment of atherosclerotic occlusive disease at the aortic bifurcation.

**Objective:** The objective was to evaluate at medium and long term, the primary patency of covered stents used in first line treatment of aorto-iliac occlusive lesions and identify predictive factors of restenosis and thrombosis (FPRT).

**Methods:** Patients from a single institution with atherosclerotic occlusive disease at the aortic bifurcation treated with covered balloon expandable stent type Advanta® V12 (Maquet) in iliac arteries were enrolled between January 2004 and December 2014. It was a retrospective study but patients were followed prospectively. A surgical consultation at one month with a control Doppler ultrasound and an annual follow up by the attending vascular physician were realized. The primary objective was primary patency. The characteristics of the population, of the lesion and those related to the intervention were analyzed by multivariate to identify FPRT.

**Results:** A total of 110 patients (151 limbs) were enrolled (86% of men, 41 kissing stent). The mean age was 61 years (39-86). The technical success was 100%. There were no intraoperative deaths and two postoperative deaths: one to the 13<sup>th</sup> day a severe sepsis because of urinary track infection and the other on the 5<sup>th</sup> day of acute coronary syndrome. The morbidity was low. The mean follow-up time was 51,3 months (0 ; 120). The primary patency was at 1, 2, 5 and 6 years: 94,2%, 92,1%, 90,4% and 87,3% respectively. Eight patients presented a thrombosis in a mean time of 31 months

and ten stenosis in 47 months. Eleven patients (10%) required further surgery within an average of 37,8 months (0,8 ; 117,7): four iterative angioplasties and seven open surgeries (bypass). Only the female gender was identified as a predictive factor of restenosis or thrombosis significantly.

**Conclusion:** In our experience, endovascular treatment with covered stent for aorto iliac occlusive lesions is a reliable technique, efficient and sustainable. The morbidity was low. In the literature, the primary patency at long-term of uncovered stents does not exceed 80 % at one year and 60 % at 5 years.

Absence of conflict of interest.

## INTRODUCTION

Peripheral Arterial Occlusive Disease (PAOD) is a complex disease of the arteries of the lower limbs. PAOD is defined as reduced arterial blood flow to the lower extremities. This reduction is mainly due to accumulation of plates limestone and cholesterol deposited on the arterial walls. This process defines atherosclerosis, which cause a reduction of arterial lumen (stenosis) or can lead to arterial occlusion (thrombosis). These injury lead to a reduction check oxygen and may lead to intermittent claudication (IC), critical limb ischemia (CLI) or ischemic skin lesions. Only one out of every four to five patients with PAOD will be symptomatic (1). Classification Leriche and Fontaine defined the various symptoms of the disease (**Table 1**). PAOD is defined by measuring an index, ankle-brachial index (ABI): this index can be measured by taking systolic blood pressure at the wrists or arms and ankles, it is the ratio of systolic blood pressure of the right ankle systolic blood pressure on the right arm and the same ratio for the left side. When this ratio is less than 0.9 to the right and / or left, it is estimated that there PAOD.

**Table 1.** Fontaine and Rutherford Classifications for PAOD.

<i>Fontaine</i>		<i>Rutherford</i>		
Stage	Clinical Description	Grade	Category	Clinical Description
I	Asymptomatic	0	0	Asymptomatic: no hemodynamically significant occlusive disease
II	IIa Walking without pain > 200m IIb Walking without pain < 200m	1	1	Mild Claudication
			2	Moderate Claudication
			3	Severe Claudication
III	Critical ischemia with rest pain, cold extremity, with improved bottom legs	II	4	Ischemic rest pain
IV	Trophic disorders with ulcers, necrosis	III	5	Minor tissue loss. Distal trophic lesions.
			IV	6

PAOD: Peripheral Arterial Occlusive Disease

## Epidemiology

In the general population the prevalence of PAOD (asymptomatic and symptomatic) is around 15% in people over 65 years and over 20 % for more than 75 years (2). Framingham Study showed an incidence of intermittent claudication of 26/10,000 in men and 12/10,000 in women (3). The main risk factors of the disease are age, tobacco use, diabetes, arterial hypertension and dyslipidaemia. Anatomically, approximately 30% of the arterial lesions in PAOD are located in the iliac arteries (4).

## Treatment

Historically, atherosclerotic occlusive disease involving the aortic bifurcation and proximal common iliac artery has been treated with open surgical by performing bypass. In 1964, Charles Dotter introduced the endovascular approach for treating aorto-iliac lesions (5,6). Then, Julio Palmaz in 1985 created the first intraluminal stent which started a breakthrough in endovascular surgery (7). The open surgical treatment showed interesting results and good long-term patency but the perioperative morbidity and mortality was important (8–12). Furthermore the endovascular treatment with the “kissing stent” technique has shown early clinical results comparable to the surgical option (13–16). Technological innovation, improvement of materials and techniques have allowed the endovascular surgery to replace open surgery in the treatment of this pathology and have reduced morbidity and mortality.

In 2007, the Trans-Atlantic Inter-Society Consensus on the Management of Peripheral Arterial Disease (TASC II) published a classification of the Aorto-iliac Occlusive Disease (AIOD) (1). Lesions are divided into four subgroups (Annexe 1). This guideline recommends endovascular therapy for the treatment of choice for type A

lesions and surgery for the treatment of type D lesions. Endovascular treatment is preferred for type B lesions and surgery for good-risk patients with type C lesions. The patient's co-morbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and type C lesions (1,6).

Endovascular treatment at the common iliac arteries consist of several techniques: the percutaneous transluminal angioplasty (PTA) (balloon dilatation), the primary stenting (to stent all lesions), or the selective stenting which consist balloon dilatation and place a stent. This technique can be used only in cases where there is a dissection or a residual stenosis. PTA is a simple and effective technique in the treatment of aorto-iliac occlusive lesions but doesn't appear to protect against restenosis and it is not recommended for severe lesions. In 1998, in a randomized study by Tetteroo et al. showed no significant difference between direct stenting and selective stenting, in terms of patency (17). Bosch, meanwhile, published in 1997 a meta-analysis comparing the two methods and showed higher technical success and patency rates after direct stenting (18). The following year, in a randomized controlled trial, no significant difference was found between the two techniques but the selective stenting appears cheaper (17). Several authors propose the use of stent systematically especially in the presence of extensive lesions (TASC C or D).

There is no general consensus on which type of stent is best for which artery. However, we know that the balloon-expandable stents are more suited for lesions on rigid arteries such as the common iliac arteries. Indeed, balloon-expandable stents are characterized by much greater radial strength compared to self-expanding stents. Moreover, the arrival on the market of PTFE covered stent offers an attractive solution.

This type of stent realizes a real endopontage and appears to limit the effects of myointimal hyperplasia intra stent and the risk of dissection and embolism during the procedure.

Problem statement

Some studies have published excellent results as regards the primary patency of PTFE-covered stents (**Table 2**). These studies are mostly retrospective, only three are comparative. They represent only a relatively small sample of patients with a short follow-up, except Chang in 2008, who compares retrospectively 71 stenting with covered stents versus 121 uncovered stents for 5 years but he study only self-expanding stents (19).

Our study aims, by relating our experience to evaluate the effectiveness of balloon expandable covered stents Advanta® V12 in the treatment of AIOD.

**Table 2.** Review of PTFE-covered stents evaluation for PAOD in the iliac artery.

Author, year	Type of study	Number patients	Type of stent	Primary patency Covered	Uncovered
<b>Lammer, 2000 (20)</b>	Prospective	61	Self-expanding	6 month: 98% 1 year: 91%	
<b>Wiesinger, 2005 (21)</b>	Prospective	60	Self-expanding	6 month: 94% 1 year: 91%	
<b>Bosier, 2007 (22)</b>	Prospective	91	Balloon-expandable	1 year: 91%	
<b>Chang, 2008 (19)</b>	Retrospective, comparative	71 covered 122 uncovered	Mostly self-expanding	5 year: 87%	5 year: 53%
<b>Sabri, 2010 (23)</b>	Retrospective, comparative	26 covered 28 uncovered	Balloon-expandable	1 year: 92% 2 year: 92%	1 year: 78% 2 year: 62%
<b>Mwipatayi, 2011 (24)</b>	Randomized controlled trial	83 covered 84 uncovered	Both	18 month: 92%	18 month: 75%
<b>Bekken, 2012 (6)</b>	Randomized controlled trial	87 covered 87 uncovered	Balloon-expandable Self-expanding	In progress	In progress

PAOD: Peripheral Arterial Occlusive Disease



## MATERIALS AND METHODS

### *Experimental design*

A retrospective review of consecutive patients from a single institution with atherosclerotic occlusive disease at the aortic bifurcation treated with covered balloon expandable stent type Advanta® V12 (Maquet) in iliac arteries was undertaken by using our database. Patients were enrolled between January 2004 and December 2014.

Endovascular therapy was considered as the first line treatment. Electronic medical records were reviewed to collect demographic data and patient follow up. Inclusion and exclusion criteria are summarized in **Table 3**. All study subjects had clinical and angiographic evidence of atherosclerotic occlusive disease involving the aortic bifurcation with unilateral or bilateral CIA stenosis or occlusion.

**Table 3.** Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Symptomatic patients according Leriche and Fontaine stages 2, 3 and 4 or sub acute ischemia or acute ischemia	No atheromatic disease
One or more significant aorto-iliac lesions (>60% stenosis or thrombosis) listed according to TASC classification	Asymptomatic lesion
Patient belongs to the French health care system	Stenosis at an aorto-bi-femoral bypass segment or at the distal anastomosis of the bypass
	Stenosis at an iliac limb extension of aortic stent graft
	Pregnancy

### *Endovascular Procedure*

All procedures were performed in the operating room by a certified vascular surgeon of the service. The endovascular indication was agreed upon during our weekly

vascular surgeon meeting. Informed consent was obtained before surgery. The procedure was performed under local anaesthesia with sedation in cases of isolated endovascular procedure and general anaesthesia for hybrid surgical procedures or when this one was recommended (agitated patients).

In most cases, femoral access was obtained by a percutaneous puncture guided by ultrasound, followed by insertion of 6-7 FR introducer sheaths in ipsilateral common femoral artery. For Kissing procedure, both common femoral arteries were punctured. In very few cases, the cross-over technique (across the aorto-iliac cross-over) from the contralateral insertion point, under fluoroscopic guidance was realized. An intravenous bolus of 50 UI kg<sup>-1</sup> of heparin was administered. Under fluoroscopy, a hydrophilic 0,035-inch guide wire was advanced through the iliac lesions via the common femoral artery access sites, with the possible assistance of a straight diagnostic catheter 4F. A Digital Subtraction Angiography retrograde was performed by the introducer, in an anterior/posterior projection. Oblique X-ray of the pelvis arterial anatomy were also obtained. For proximal lesions, DSA was obtained by a pigtail placed in distal aorta. The stent dimensions were chosen by visual estimation to fit vessel diameter at best with a length exceeding the lesion length by 5mm proximally and 10mm distally. The diameters of the selected stent were usually oversized 10%-20% relative to the treated iliac arteries. Lesions were treated with as few stents as possible and adjacent stents over-lapped by 1 cm. Pre-dilation was performed when it was necessary to facilitate the deployment the stent. Advanta® V12 stents were deployed by inflation of the balloon to the desired pressure according to manufacturer recommendations. Simultaneous stent deployment was performed when the kissing balloon/stent technique was necessary (**Figure 1 and 2, Annexes**). Post dilatation was realized with the same balloon, in case

of residual stenosis. The technical result of the procedure was evaluated by DSA. An additional endovascular or surgical procedure was performed if necessary. Groin closure was accomplished via manual compression during 15-20 minutes.

A prophylactic dose of low-molecular-weight heparin was given during hospitalisation to prevent venous thrombo-embolic events. Postoperatively, patients were prescribed Aspirin® (75 or 160 mg day<sup>-1</sup>) or Clopidogrel® (75 mg day<sup>-1</sup>). When patients were under oral anticoagulant treatment, Aspirin® was the only anti-platelet agent added.

### *Follow up*

The patients were followed prospectively and different clinical and radiological data were stored in our database. Our monitoring protocol consisted of a surgical consultation after a month from the surgery with a control Doppler ultrasound and an annual follow up by the attending vascular physician. Finally each patient, physician, and vascular medicines were contacted by telephone at follow-up for evaluation of symptoms.

### *Objectives and definitions*

The primary objective was primary patency. Secondary objectives were primary assisted patency, secondary patency, primary clinical success, technical success, morbidity and mortality in the immediate postoperative (<30 days) and remotely (>30 days), in-stent restenosis (ISR), in-stent thrombosis. Finally, we sought to identify predictive factors of restenosis or thrombosis.

Detailed definitions of outcome are:

- Primary patency was defined as patency without any percutaneous or surgical intervention in the treated segment or in the adjacent areas (25).
- Primary assisted patency was defined as a patent artery that underwent further endovascular intervention to improve patency.
- Secondary patency was defined as occlusion of the iliac segment requiring open or endovascular recanalization or bypass surgery (19).
- The rate of primary clinical success, defined as the disappearance or improving of the symptoms initially presented by the patient in the absence of any act of secondary revascularization or major amputation.
- Technical success was defined as achievement of a final residual diameter stenosis of <30% on the procedural completion angiogram.
- Morbidity was divided into minor and major complications. Minor complications are those following procedure (within the first month) and not requiring further treatment and not extending hospital stay. Major complications required re-intervention or delay (more than 24 h) in patient discharge.
- ISR were assessed by duplex ultrasound and was defined by restenosis of more than 50%.
- The diagnosis of stent thrombosis was considered when occlusion was seen on duplex scan without any previous sign of restenosis.

### Statistical analysis

Results were expressed as numbers and percentages for categorical parameters, and as the mean and standard deviation for continuous quantitative variables with normal distribution or median and percentiles if necessary. Univariate Cox regressions

were used to evaluate the role of the risks factors to detect restenosis or thrombosis of stent. A multivariate risk model was constructed using a backward stepwise Cox model strategy ( $P \leq 0.05$  for model entry and  $P \leq 0.10$  for model retention). To form this risk model for restenosis or thrombosis of stent, gender, BMI, HTA, dyslipidemia, diabetes, serum creatinine values, smoking, ASA score (American Society of Anesthesiologists), history of coronary disease, history of aortic surgery, or carotid artery surgery, or history of aortic bifurcation endovascular procedure, treatment with Plavix® or Aspirine®, TASC classification, history of cancer, localization of lesion and degree of stenosis were considered in the model selection process. The proportional-hazards assumption of the Cox model was checked separately for each covariate by the stcox PH-assumption test (stata procedure) after performing the cox analyses. The results were presented using the hazards ratio (HR) with a 95% confidence interval (CI). The level of significance was set at  $p < 0.05$ . Statistics were conducted with STATA-13.1 software (StataCorp, College Station, TX, USA).

## RESULTS

### *Patient's characteristics and demographics*

A total of 110 patients (151 limbs) were enrolled. The study population was composed of 95 men (86,4%) and 15 women (13,6%), and their median age at presentation was 61 years [55 ; 68]. Demographic characteristics are presented in **Table 4**. Indications for intervention included 89 patients (80,9%) for claudication, 4 patients (3,6%) for CLI, 12 (10,9%) for ischemic skin lesions and 5 (4,5%) for acute or sub-acute ischemia.

**Table 4.** Baseline patients' characteristics and medical history.

<i>Variables</i>	
Age, years (mean $\pm$ SD)	61 $\pm$ 10
Male sex, n (%)	95 (86,4)
Smokers, n (%)	105 (95, 5)
Active	59 (53, 6)
Previous	46 (41,8)
Hypertension, n (%)	65 (59,1)
Hyperlipidemia, n (%)	67 (60,9)
Diabetes, n (%)	31 (28,2)
Obesity (BMI > 25), n (%)	55 (50)
Serum creatinine values (mean $\pm$ SD)	93 $\pm$ 58
Coronary artery disease, n (%)	39 (35,5)
Myocardial infarction	13 (11,8)
Coronary Angioplasty/ stenting	14 (12,7)
Coronary artery bypass surgery	12 (10,9)
American Society of Anesthesiologists, n (%)	
Grade I	8 (7,3)
Grade II	55 (50)
Grade III	43 (39,1)
Grade IV	4 (3,6)
Leriche and Fontaine stage of PAOD, n (%)	
2	89 (80,9)
3	4 (3, 6)
4	12 (10,9)
Sub acute ischemia	3 (2,7)
Acute ischemia	2 (1,8)

BMI, Body Mass Index ; SD, Standard Deviation ; PAOD, Peripheral Arterial Occlusive Disease

### *Intra and Peri-operative management*

**Table 5** presents the outcomes of 110 endovascular procedures. Local anaesthesia with sedation was performed in 90 cases (81,8%), 11 general anaesthesia (10%) was performed for hybrid surgical procedures and 9 (8,2%) for patient comfort. An antegrade approach was realized for 150 limbs (99,3%), a cross over approach for one limb (0,7%) and 41 Kissing procedures (37,3%) were performed. Femoral access was obtained by a percutaneous puncture in 142 cases (94%). For 9 limbs (6%), femoral access was obtained by surgical approach. Seven lesions (4,7%) were restenosis.

According to the TASC II classification, 55 patients (50%) were classified as TASC A, 32 (29,1%) as TASC B, 5 (4,5%) as TASC C and 18 (16,4) as TASC D. A total of 120 lesions presented stenosis more than 70%. There were 19 thrombosis (12,7%). In 35,8% of the cases a femoro-popliteal lesion was associated. Mean stented segment was  $44,4\text{mm} \pm 7,9$  and the mean number of the stent implanted per patient was  $1,3 \pm 0,3$ . Concomitant procedure was performed for 18 patients (16,4%): 6 (5,5%) by endovascular repair, 11 (10%) by open repair and 1 (0,9%) by mixt procedure. No conversion to open aorto-iliac surgery during the perioperative period were reported. The technical success was 100%. During the perioperative period two patients died: one patient aged 78, with coronary artery disease presented severe sepsis caused by urinary track infection to the 13<sup>th</sup> day post operatively, the second patient aged 85 years, suffering from severe coronary artery disease, died on the 5th day of acute coronary syndrome. Eight major complications (7,3%) led to an increase in the duration of hospitalization and/or re-intervention: two puncture site hematomas evolved to pseudo aneurysm, one deep vein thrombosis, one distal embolism, one occlusive syndrome, three early thrombosis. One minor hematoma appeared after a week and is absorbed without intervention. The average length of hospital stay was 3,1 [1 ; 30].

**Table 5.** Intra-operative and perioperative data.

<i>Variables</i>	
<b>Characteristics of the lesions</b>	
TASC II classification of the lesions, n (%)	
A	55 (50)
B	32 (29,1)
C	5 (4,5)
D	18 (16,4)
Approach, n (%)	
Crossover	1 (0,7)
Anterograde	150 (99,3)
Kissing, n (%)	41 (37,3)
Degree of stenosis, n (%)	
60-70%	12 (7,9)
≥70%	47 (31,1)
≥80%	48 (31,8)
≥90%	25 (16,6)
Thrombosis	19 (12,6)
Location of the lesion, n (%)	
Ostial	112 (74,2)
Proximal	37 (24,5)
Full axis	2 (1,3)
Femoro-popliteal lesions associated, n (%)	54 (35,8)
<b>Characteristics of the stents</b>	
Length of stent, n (%)	
22 mm	2 (1,3)
38 mm	135 (89,4)
59 mm	26 (17,2)
Number of stent per patient, n (mean ± SD)	1,3 ± 0,3
Number of stent implanted, n (%)	
1	139 (92,1)
2	20 (13,2)
3	4 (2,6)
Diameter of implanted stent, n (%)	
6	2 (1,3)
7	16 (10,6)
8	109 (72,2)
9	29 (19,2)
10	7 (4,6)
Pre dilatation, n (%)	42 (27,8)
Post dilatation, n (%)	5 (3,3)
Associated procedures, n (%)	
Endovascular repair	6 (5,5)
Aorta	1 (0,7)
External iliac artery	4 (2,3)
Common iliac artery controlateral	1 (0,7)
Open repair	11 (10)
Femoral endarterectomy	7 (6,4)
Femoro-popliteal bypass	1 (0,7)
Iliac and popliteal thrombectomy ± aponevrotomy	3 (3,3)
Mixte	1 (0,9)
Technical Success, (%)	100
Intraoperative complications, n (%)	3 (2,7)
Postoperative Serum creatinine values (mean ± SD)	76 ± 56
Duration of hospital stay, d (mean ± SD)	3,1 ± 4,9
Perioperative complications, n (%)	
Minor	1 (0,9)
Major	8 (7,3)
Death (<30th day), n (%)	2 (1,8%)

TASC, Trans-Atlantic Inter-Society Consensus



## Outcomes

The mean follow-up time was 51,3 months (0 ; 120). All patient have been followed up. Twenty-two patients died during the follow up (**Table 6**).

**Table 6.** Outcomes post-operative

Variables	
Death (>30 <sup>th</sup> day), n (%)	22 (20)
Pulmonary neoplasia	7 (35)
Head and neck cancer	2 (10)
Gastric cancer	1 (5)
Hematologic malignancies	4 (20)
Bladder cancer	1 (5)
Unknown	7 (35)
In-stent restenosis (ISR), n (%)	10 (9,1)
In-stent thrombosis, n (%)	8 (7,3)

The primary clinical success at the end of follow up was 82,7% (91 patients) (**Figure 4**).

Among the 89 patients followed and treated for PAOD stage 2:

- A disappearance of intermittent claudication (n = 74) or an improvement of claudication (n = 1) has been reported in 84,3% of cases, without re-intervention.
- Six patients did not have symptomatic improvement: they presented no stenosis or thrombosis and two of them had femoro-popliteal lesions.
- One patient treated for bilateral lesions TASC B presented a stenosis after 44,9 months. He still refuses further surgery.
- A disappearance of intermittent claudication has been reported in seven patients with re-intervention (**Table 7**): four patients presented a stenosis and three a thrombosis. Five of seven patients were active smokers.

Among the four patients followed and treated for CLI, 100% of patients were

asymptomatic at the end of follow up.

For the 12 patients followed and treated for PAOD stage 4, 11 patients (91,7%) were asymptomatic and one patient (8,3%) had healed but still presented with claudication. This patient was an active smoker, ached chronic renal failure on dialysis, in addition he had femoro-popliteal lesions, external and common iliac arteries. An external iliac artery angioplasty was realized while the procedure. The patient died of lung cancer after one year.

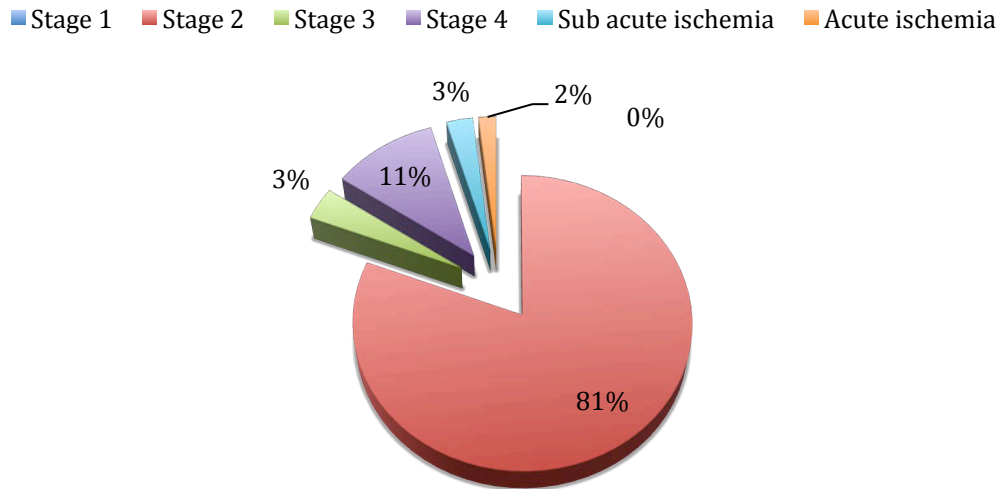
The two patients treated for acute ischemia 100% were asymptomatic. Finally, two of three patients (66,7%) treated for sub-acute ischemia were symptomatic, and one patient suffered to claudication.

**Table 7.** Characteristics of patients treated for claudication, improved with re-intervention.

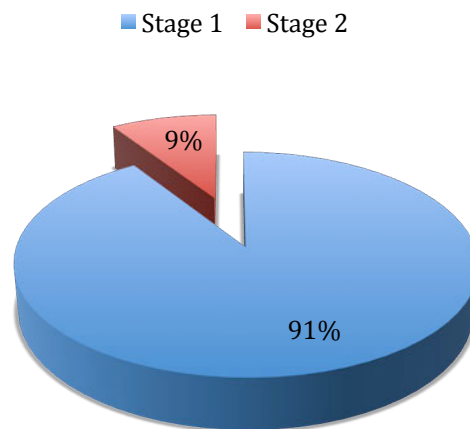
Lesion	Occurrence delay (month)	Initial lesion	TASC	Length of stent	Re intervention	Delay (month)
Thrombosis	117,7	Stenosis	C	7 x 38 / 8 x 38 Kissing	Aorto-bi-femoral bypass	118
Thrombosis	10,3	Thrombosis	D	8 x (22+38+59) 7 x 38 Kissing	Transfemoral amputation, Axillo-bi-femoral bypass Aorto-bi-femoral bypass	8 10 22
Thrombosis	15,1	Stenosis	B	8 x 59	Thrombectomy + Axillo-bi-femoral bypass	15,3
Stenosis	33,7	Pre thrombosis	B	7 x 38 / 7 x 38 Kissing	Angioplasty	36,9
Stenosis	8,6	Stenosis	B	8 x 38	Angioplasty	8,7
Stenosis	11,3	Stenosis	A	8 x 38 / 8 x 38 kissing	Angioplasty Left Aorto-femoral bypass + femoro-femoral cross over bypass	11,3 88
Stenosis	70,3	Stenosis	A	10 x 38	Transfemoral amputation	72

TASC, Trans Atlantic Inter-Society Consensus

## Initial Clinical Status



## Clinical Status at the end of follow up



**Figure 4.** Clinical outcomes at the end of the follow up. Patients classified by Leriche and Fontaine Classification.

Eighteen patients (16,4%) presented with stenosis or a thrombosis (**Table 8**), three were detected before the first month, three before the sixth month, two before the first year, and ten beyond twelve months. The initially treated iliac lesions were classified TASC A in 6 cases, TASC B in 7 cases, TASC C in 3 cases and TASC D in 2 cases.

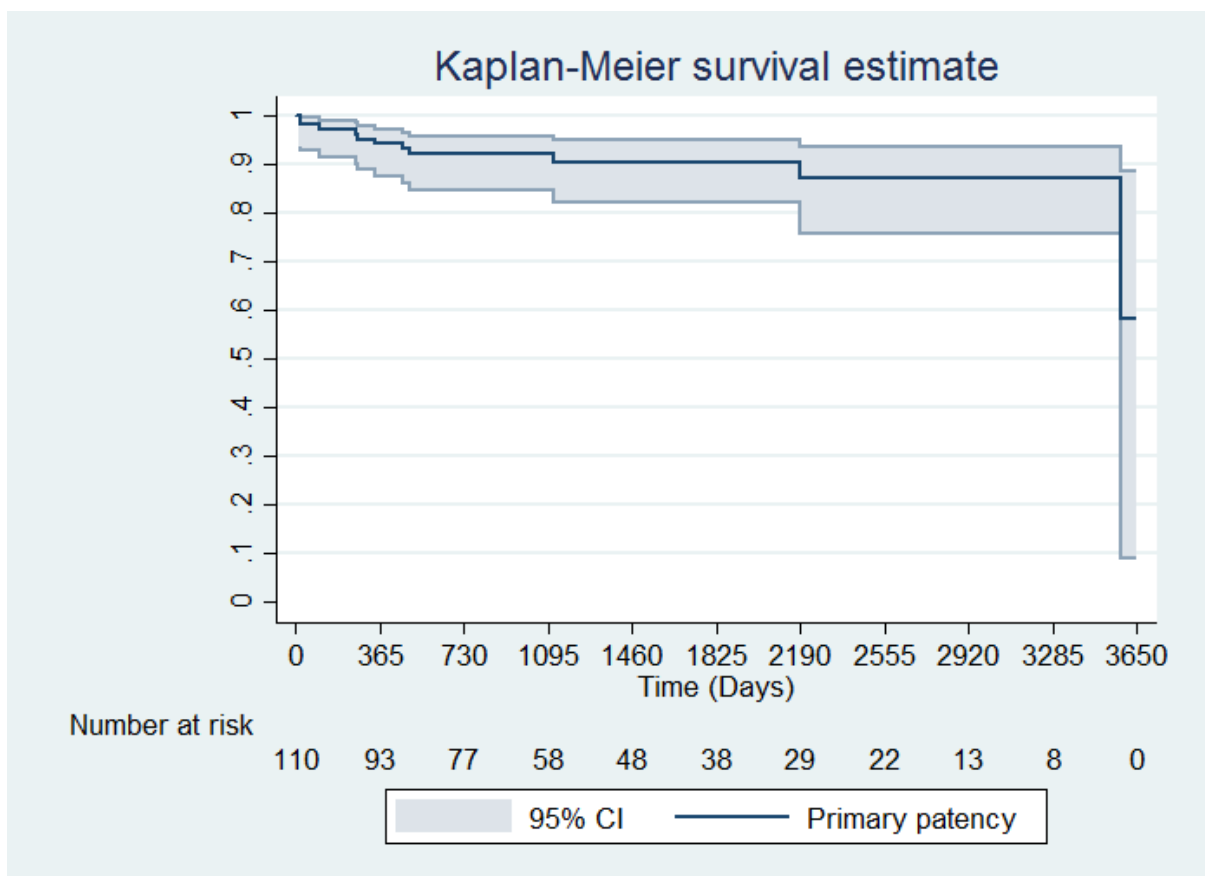
**Table 8.** Details of re-stenosis and thrombosis.

Lesions	Occurrence delay (day)	Initial PAOD stage	Kissing	Initial lesions	TASC	Length of sten	Re intervention
Thrombosis	1	4	-	Thrombosis	D	9 x 38 / 10 x 38	Iliac thrombectomy
Thrombosis	2	2	Kissing	Thrombosis	D	8 x (22+38+59) / 7 x 38	Transfemoral amputation, Axillo-bi-femoral bypass, Aorto-bi-femoral bypass
Thrombosis	14	4	-	Thrombosis	B	8 x 38	Aorto common femoral bypass
Thrombosis	67	2	-	Stenosis 70%	B	7 x 38	-
Thrombosis	94	4	Kissing	Stenosis 80%	C	9 x 38	Bilateral iliac angioplasty Aorto-bi-femoral bypass
Thrombosis	458	2	-	Stenosis 70%	B	8 x 59	Thrombectomy, Axillo-bi-femoral bypass
Thrombosis	2423	Sub acute ischemia	-	Stenosis 70%	A	9 x 38	-
Thrombosis	3578	2	Kissing	Stenosis 70%	C	7 x 38 / 8 x 38	Aorto-bi-femoral bypass
Stenosis	90	2	Kissing	Stenosis 90%	A	(9 x 38) x 2	-
Stenosis	103	2	Kissing	Stenosis 70%	A	(8 x 38) x 2	-
Stenosis	263	2	-	Stenosis 80%	B	8 x 38	Angioplasty
Stenosis	342	2	Kissing	Stenosis 70%	A	(8 x 38) x2	Angioplasty, Left Aorto-femoral bypass + femoro-femoral cross over bypass
Stenosis	497	Sub acute ischemia	-	Stenosis 80%	A	8 x 38	Angioplasty
Stenosis	1024	2	Kissing	Stenosis 90%	B	(7 x 38) x 2	Bilateral iliac angioplasty
Stenosis	1364	2	Kissing	Thrombosis (right) Stenosis 60%	B	(8 x 38) x 2	-
Stenosis	2136	2	-	Stenosis 90%	A	10 x 38	Transfemoral amputation
Stenosis	2208	2	-	Stenosis 80%	C	7 x 38	-
Stenosis	2425	2	Kissing	Stenosis 80% right, 60% left	B	8 x 38 / 8 x 59	-

PAOD, Peripheral Arterial Occlusive Disease; TASC, Trans-Atlantic Inter-Society Consensus.

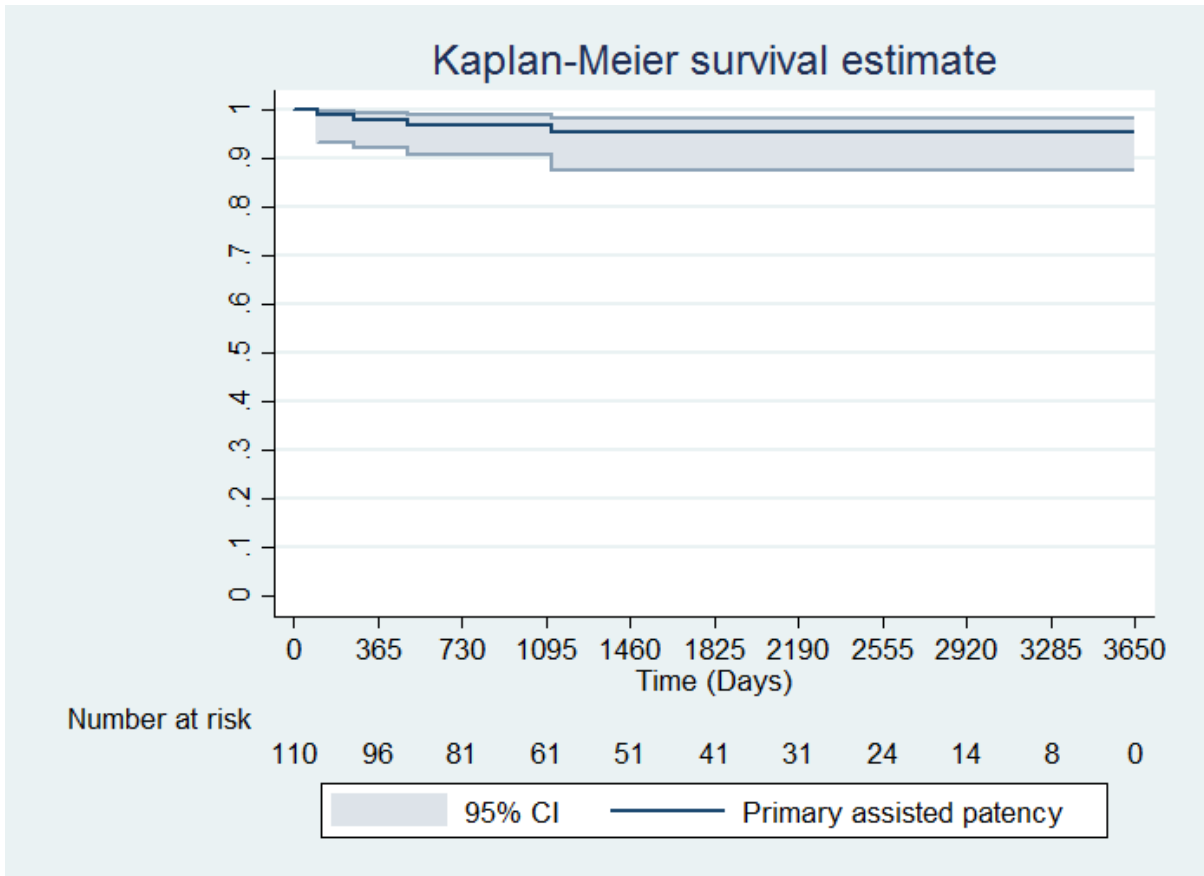
Eleven patients (10%) required further surgery within an average of 37,8 months (0,8 ; 117,7): four iterative angioplasties and seven open surgeries (bypass).

The primary patency rate (**Figure 5**) was 98,1% (92,8 ; 99,5) at one month, 94,2% (87,5% ; 97,4%) at one year, 92,1% (84,7% ; 96%) at two years, 90,4% (82,2% ; 95%) at five years and 87,3% (75,9% ; 93,5%) at six years .



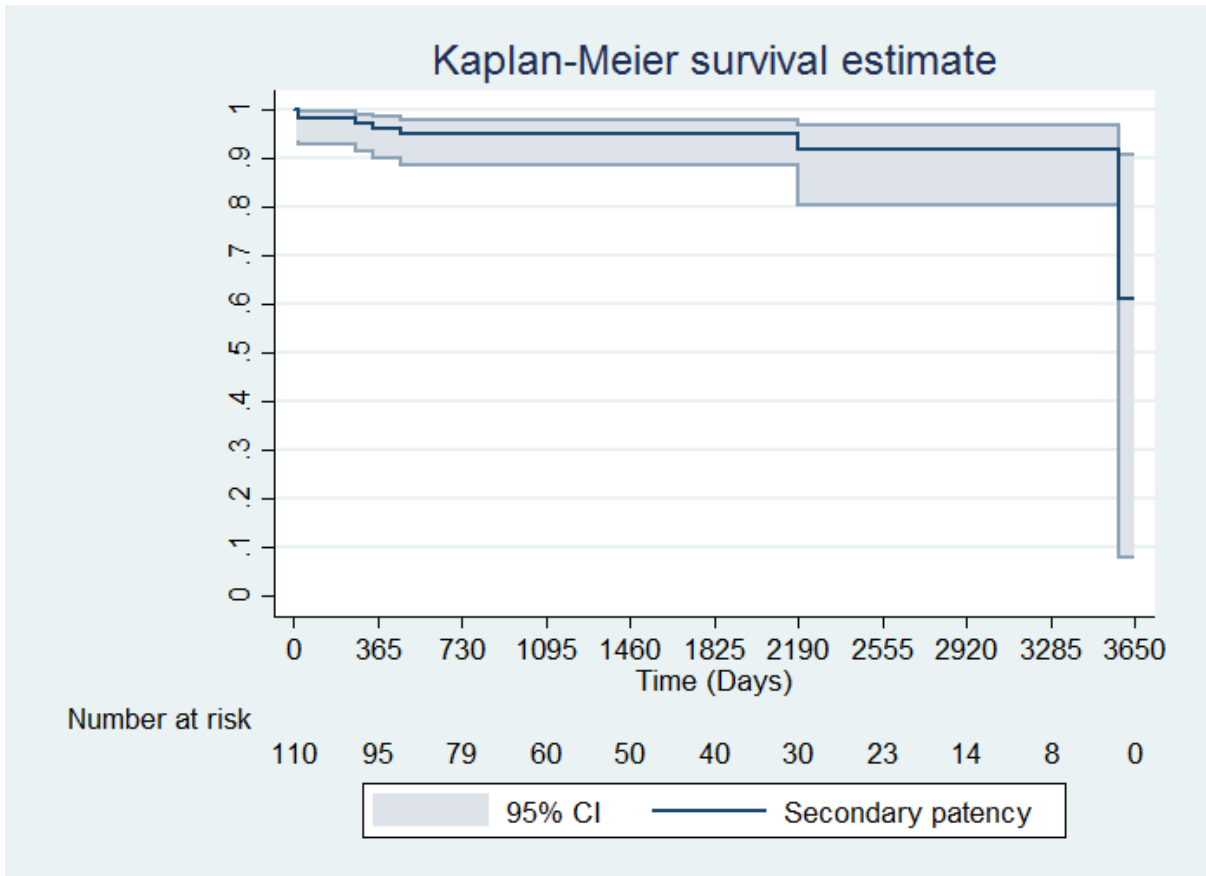
**Figure 5.** Primary patency.

The primary assisted patency rate was 98% (92,4 ; 99,5%) at one year, 97% (90,8% ; 99%) at two years, 95,3% (87,7% ; 98,3%) at five years and 95,3% (87,7% ; 98,3%) at six years (**Figure 6**).



**Figure 6.** Primary assisted patency.

The secondary patency rate was 98,2% (92,8% ; 99,5%) at one month, 96,2% (90,1% ; 98,5%) at one year, 95,1% (88,6% ; 97,9%) at two years, 95,1% (88,5% ; 97,9%) at five years and 91,9% (80,5% ; 96,8%) at six years (**Figure 7**).



**Figure 7.** Secondary patency

Significantly in univariate analysis, only female gender was identified as a predictive factor of restenosis or thrombosis Hazard ratio= 4.20 [1.41 ; 12.48], p= 0,010 and arterial hypertension and dyslipidemia as protective factors Hazard ratio= 0.37 [0.14 ; 0.99], p= 0,049 and 0.39 [0.15 ; 0.99], p= 0,050 respectively. These results were still significant after adjustment with multivariate analysis **(Table 9 and 10)**.

**Table 9.** Univariate Analysis – Risk factors of re stenosis or thrombosis.

N=110	Absence of stenosis or thrombosis n=92	Presence of stenosis or thrombosis n=18	HR [IC à 95%]	P value
Female gender (2)	10.9% (10)	27.8% (5)	4.20 [1.41 ; 12.48]	<b>0.010 **</b>
BMI, mean ± SD	25.56 ± 3.50	25.32 ± 4.78	0.95 [0.83 ; 1.09]	0.460
HTA, % (n)	64.1% (59)	33.3% (6)	0.37 [0.14 ; 0.99]	<b>0.049 *</b>
Dyslipidemia, % (n)	65.2% (60)	39.9% (7)	0.39 [0.15 ; 0.99]	<b>0.050 *</b>
Diabetes, % (n)	32.6% (30)	5.6% (1)	0.16 [0.02 ; 1.22]	0.078
Créatinine value	79 [69 ; 100.5] <sup>1</sup>	75.5 [67 ; 87] <sup>1</sup>	0.98 [0.96 ; 1.01]	0.166
Smoker (Active), % (n)	51.1% (47)	66.7% (12)	1.65 [0.62 ; 4.41]	0.314
ASA, % (n)				
1	7.6% (7)	5.6% (1)	-	-
2	48.9% (45)	55.6% (10)	2.24 [0.27 ; 18.7]	0.454
3	40.2% (37)	33.3% (6)	2.34 [0.25 ; 21.5]	0.454
4	3.3% (3)	5.6% (1)	5.62 [0.32 ; 97.6]	0.236
Coronary history, % (n)	39.1% (36)	16.7% (3)	0.40 [0.12 ; 1.40]	0.153
Carotid surgery history, % (n)	8.7% (8)	11.1% (2)	1.25 [0.29 ; 5.49]	0.764
Aortic surgery history, % (n)	1.1% (1)	5.6% (1)	2.56 [0.34 ; 19.48]	0.363
Aorto-iliac endovascular history, % (n)	12% (11)	11.1% (2)	0.81 [0.18 ; 3.69]	0.781
Localization, % (n)	69.6% (64)	77.8% (14)	1.77 [0.58 ; 5.41]	0.319
Plavix®, % (n)	53.3% (49)	72.2% (13)	1.54 [0.54 ; 4.37]	0.421
Aspirin®, % (n)	59.8% (55)	44.4% (8)	0.89 [0.34 ; 2.33]	0.818
TASC, % (n)				
A	53.3% (49)	33.3% (6)	-	-
B	27.2% (25)	38.9% (7)	2.13 [0.71 ; 6.40]	0.176
C	2.2% (2)	16.7% (3)	3.34 [0.77 ; 14.43]	0.106
D	17.4% (16)	11.1% (2)	1.02 [0.21 ; 5.09]	0.977
History of cancer, % (n)	17.4% (16)	22.2% (4)	1.40 [0.45 ; 4.30]	0.558
Degree of lesion, % (n)				
<70	6.5% (6)	5.6% (1)	-	-
≥70 et <80	31.5% (29)	33.3% (6)	0.97 [0.12 ; 8.13]	0.977
≥80 et <100	48.9% (45)	44.4% (8)	0.96 [0.12 ; 7.73]	0.972
100	13% (12)	16.7% (3)	1.37 [0.14 ; 13.66]	0.790

Univariate analysis: Cox Model; HR: Hazard Ratio [Confidence Interval à 95%]; <sup>1</sup>=median [25% ; 75%]; BMI, Body Mass Index ; SD, Standard Deviation; TASC, Trans Atlantic Inter-Society Consensus, ASA: American Society of Anesthesiologists; HTA, arterial hypertension.



**Table 10.** Univariate and multivariate analysis – Risk factors of re stenosis and thrombosis.

N=110	Univariate analysis HR [IC 95%]	P value	Multivariate analysis HR [IC 95%]	P value
Female gender	4.20 [1.41 ; 12.48]	0.010 **	5.74 [1.85 ; 17.81]	0.002
HTA	0.37 [0.14 ; 0.99]	0.049 *	0.32 [0.12 ; 0.89]	0.029
Dyslipidemia	0.39 [0.15 ; 0.99]	0.050 *	0.39 [0.15 ; 1.02]	0.056

Univariate and multivariate Analysis: Cox model, HR: Hazard Ratio [Confidence interval 95%]; HTA: arterial hypertension;

## DISCUSSION

Our study shows excellent primary, primary assisted and secondary patency rate of covered stent in PAOD with low morbidity and mortality.

In 110 procedures we studied, the same technical problem occurred twice: the inability to pass the device through a calcified pre-thrombotic primary iliac stenosis, while the 0.035-inch hydrophilic guide had crossed the lesion without difficulty. This led to uncrimping of the stent that was released just below the lesion. The two patients in whom this occurred were being treated for bilateral pre-thrombotic lesions. A pre-dilatation was performed and a new stent was implanted. During follow-up neither of these stents became stenosed or thrombotic.

For all treated lesions only 28% were pre-dilated, in contrast to the series reported by Bosiers et al. in which pre-dilation with a 5 mm diameter balloon was systematic and this type of problem was not encountered (22).

In our cohort there were two deaths (1.8%) within 30 days post-surgery but the causes were not directly related to the endovascular procedure. The rate of complications related to the procedure was 8.2%, including three early thrombosis.

This rate is comparable to that in the literature where the rate varies between 2.7 and 24% (26). The first case of early re-thrombosis occurred in an active smoker treated for bilateral claudication with very severe iliac lesions. He presented with a thrombosis of the entire right iliac axis and stepped tight stenosis along the whole left iliac axis requiring the implantation of several stents. This was probably a poor indication for stenting and a conventional surgical treatment should have been proposed according to the current TASC guidelines lesions as his lesions were classified as TASC D. Eight months later he underwent transfemoral amputation of the lower right limb, a year after this an axillo-femoral bridging graft and finally a left femoral artery bypass two years after the first procedure. The second case of early re-thrombosis also occurred in an active smoker treated for severe lesions (TASC class D). He presented thrombosis of the whole left iliac axis requiring the placement of two stents and a non-symptomatic contralateral primary iliac thrombosis. This patient would have received surgical treatment but was a fragile patient, ASA 4, and died less than a year after the procedure from acute leukemia. Finally, the last case of early re-thrombosis occurred in an active smoker, ASA 3, treated for TASC B lesions with left iliac thrombosis. No pre-dilatation before stenting had been done. The patient underwent aorto-left femoral coronary bypass surgery one month after the initial procedure. Thus, it was observed that early re-thrombosis occurred in patients with severe lesions for whom conventional surgery would have been proposed if they had not presented a contra-indication to aortic surgery.

Approximately 80% of patients in our study had TASC class A or B lesions; and those with TASC C and D lesions were for the most part fragile cases with an ASA score of 3 or 4, contra-indicative of aortic surgery. We had respected the current guidelines on the therapeutic management of AIOD in our operating procedures. However, some

authors report primary patency rates for the treatment of severe iliac lesions (TASC C and D) of 88% at 6 months, 82% at 12 months and 78% at 24 months with systematic use of self-expanding stents and of 87% at 6 months and 70% at 12 months when using covered stents (Wallgraft® or Viabahn®) (27,28). A review of the literature by Jongkind et al. found primary and secondary patency rates of 60 to 80% and 80 to 98% respectively (29). These results must be considered alongside conventional surgery (aorto-femoral bypass) that achieves a primary patency rate at 5 years of 91% in claudication patients and 87% in patients with critical limb ischemia, with a perioperative mortality rate close to 2% (8,30).

In the literature, iliac stents are generally associated with good outcomes and for the most part intra-stent myo-intimal hyperplasia appears to be responsible for late failures of stenting (7). Although stents are used to correct an initial residual stenosis or localized dissection occurring after the fracture of the atherosclerotic plaque, they increase the formation of micro-thrombi, induce inflammatory reactions and myo-intimal hyperplasia, all sources of re-stenosis. However, the use of steel stents covered with a PTFE membrane is considered to have several advantages. These stents can be used to treat an arterial rupture during the same procedure, a rare but extremely serious complication, which we were not confronted with in our series. The use of covered stents for the treatment of this complication has been described by Scheinert et al. with immediate success of 100% and a primary patency rate of 87% at 2 years (31).

The presence of the PTFE covering theoretically restricts fragmentation of the plaque during angioplasty and thus limits the risk of peripheral embolisms. However, in

our series, one patient, a 69 year-old male former smoker with dyslipidemia and treated for claudication, had this complication. He had severe lesions of the aortic bifurcation classified TASC D. Stenosis of the terminal aorta and iliac ostial stenosis was treated with one aortic stent, two iliac stents in a "kissing" configuration and one stent in right iliac artery. Sub-acute ischemia appeared immediate postoperatively in his left leg and a secondary femoral and popliteal embolectomy was performed. The risk of embolization appears greatest when the lesions are ulcerated or recanalization is attempted, with a rate of peripheral embolism of up to 24% in cases of simple angioplasty (32,33). This complication appears to be largely underestimated as it is most often asymptomatic, but it has been demonstrated in a histological study by Karnabatidis et al. to occur in up to 70% of cases (34). Moreover, it would appear that lesions of the aorto-iliac bifurcation are more at risk of embolism, such that some authors prefer using the "kissing" technique for this type of lesion (35). This is the case of our patient who should have been entitled to aortic surgery according to the TASC 2 guidelines.

Finally, the use of a covered stent seems to intuitively limit intra-stent myointimal hyperplasia. It creates a mechanical barrier between the blood and the endothelium possibly restricting the stimulation and proliferation of smooth muscle cells and especially their migration through the mesh of the stent. According to some studies the non-porosity of the PTFE membrane appears to limit this hyperplasia and thus reduce the risk of restenosis (36,37). For Sabri, the difference in primary patency observed between the use of a covered stent and a bare stent is clearly due to the absence of intra-stent myointimal hyperplasia and better fluid dynamics (23). However, Sangiorni et al. in their anatomico-pathological study of pig peripheral arteries

did not find any difference when looking at micro-thrombi, local inflammatory phenomena or myo-intimal hyperplasia between the use of bare steel or stents covered with a PTFE membrane (38). All the same, it should be noted that the bare stents were deployed in the renal arteries while covered stents were placed in the iliac and renal arteries and the aortas. The comparison was thus probably biased. In addition, most of the results were not significant. Of the 10 cases of re-stenosis, 3 cases of restenosis were described as being at the end of the stent or downstream. While such lesions may be related to the progression of the atheromatic disease, they could also have been myo-intimal hyperplastic lesions since they were at the end of the stent where the endothelium is traumatized by the stent, without the PTFE membrane performing its barrier role. Furthermore, two cases of intra-stent restenosis were detected by ultrasound but did not need iterative angioplasty. This type of restenosis can be explained by myo-intimal proliferation associated with excessive porosity or a tear in the PTFE membrane.

In our series the rates of primary, primary-assisted and secondary patencies at one month, one year and in the long term were slightly higher than those from the most recent series reported the literature that used iliac angioplasty with selective or systematic stenting (**Table 10**). The primary patency rate obtained by Bosiers et al, the only other study that evaluates the Advanta V12 covered stent, was 91.1% at one year compared with 94,2% in our study (22). This difference can be explained by the fact that Bosiers studied these stents predominantly in lesions of the aortic bifurcation, an area known to have a higher risk of restenosis or re-thrombosis. Chang et al. are the only authors to present long-term results with primary patency at 5 years of 87% against 90,4% in our series (19). However, in their series, Chang essentially assess self-

expanding stents in patients with severe lesions classified as TASC C or D, while in our series about 80% of patients had lesions classified as TASC A or B. A clear difference is also seen between our long-term results and those of bare stents. Indeed, the primary patency of bare stents observed by Chang was 53% at 5 years against 90,4% for the covered stents used in our series.

The various series described to date do not indicate whether the long-term decrease in patency is due to intra-stent restenosis, to stenosis at the ends of the stent or atheromatous lesions in the iliac axis. It is often said that intra-stent restenosis by myo-intimal hyperplasia is the main cause of late stent failure but its proportion is difficult to specify. This was the case in our study where the evaluation of restenosis was not standardized and the vascular doctors did not specify the location of all detected restenosis.

**Table 10.** Aorto-iliac Stenting. Literature review.

	Stenting Primary or Selective	Type of stent	Number patients (limbs)	TASC,	%	Artery,	%	Primary patency
<b>Kudo, 2005 (39)</b>	Selective - Angioplasty (77%) - Stents (23%)	Balloon- expandable	104 (151)	A B C D	26 47 36 3	AIP AIE AIP+AIE	29 20 61	90% at 6 m. 76% at 1 y. 63% at 22 m.
<b>AbuRahma, 2007 (26)</b>	Primary	Self-expanding	110 (149)	A+B C+D	55,5 44,5	AIP AIE AIP+AIE	60 21 19	98% at 1 y. 94% at 2 y.
<b>AbuRahma, 2007 (26)</b>	Selective	Self-expanding	41 (41)	A+B C+D	68 32	AIP AIE AIP+AIE	71 17 12	83% at 1 y. 78% at 2 y.
<b>Reekers, 2002 (40)</b>	Selective	Balloon- expandable	126 (143)	-	-	AIP AIE AIP+AIE Aorta	49 31 17 3	94% at 6 m. 89% at 1 y.
<b>Becquemin, 1999 (41)</b>	Selective	-	235 (281)	-	-	AIP AIE	56,5 43,5	86,6% at 1 y. 81,2% at 2 y.
<b>Timaran, 2001 (42)</b>	Both	Both	189 (247)	A B C D	19 51 25 5	AIP AIE AIP+AIE	- - -	88% at 1 y. 74% at 3 Y.
<b>Bosier, 2007 (22)</b>	Primary	Balloon- expandable (Advanta V12)	65 (91)	-	-	AIP AIE AIP+AIE Aortic bifurcation	23,3 12,1 3,3 61,5	91,1% at 1 y.
<b>Lammer, 2000 (20)</b>	Primary	Self-expanding covered	127 (61)	A B C	38* 56 7	AIP AIE	52,5 47,5	98,4% at 6 m. 91,2 at 1 y.
<b>Wiesinger, 2005 (21)</b>	Primary	Self-expanding covered	98 (60)	-	-	AIP	-	94% at 6 m. 91% at 1 y.
<b>Chang, 2008 (19)</b>	Primary	Mostly self- expanding	171 (193) 71 covered 122 uncovered	C D	39 61	AIP	-	Covered: 87% at 5 y. Uncovered: 53% at 5 y.
<b>Sabri, 2010 (23)</b>	Primary	Both	54 (54) 26 covered 28 uncovered	-	-	Aortic bifurcation	-	Covered: 92% at 1 and 2 y. Uncovered: 78% at 1 y. 62% at 2 y.
<b>Mwipatayi, 2011 (24)</b>	Primary	Both	125 (167) 83 covered 84 uncovered	B C D	62,1** 27,1 10,7	AIP	-	Covered: 92% at 18 m. Uncovered: 75% at 18 m.
<b>Bekken, 2012(6)</b>	Primary	Both	174 87 covered 87 uncovered	-	-	AIP	-	In progress
<b>Our study, 2016</b>	Both	Balloon- expandable (Advanta V12)	110 (150)	A B C D	50 29,1 4,5 16,4	AIP	-	<b>98,1% at 1 m. 94,2% at 1 y. 90,4% at 5 y. 87,3% at 6 y.</b>

TASC, Trans Atlantic Inter-Society Consensus ; y. = year ; m. = month.

Among the 18 cases of restenosis or re-thrombosis 3 had lesions of the downstream external iliac arteries, of which 33.3% were TASC A lesions and 38.9% TASC B lesions. It is clear that lesions of the EIA (13,42) and severe pelvic disease (39) are associated with a decreased primary patency rate. Similarly, a degradation of the downstream arterial bed (13,43), female gender (42) and active smoking (39) are considered as factors that reduce primary patency. In our study only female gender was found to be predictive of restenosis and/or significant re-thrombosis. This may be due to an insufficient power of our study due to the small population size and the retrospective approach, a source of missing baseline data and making the data collection and follow-up difficult. Dyslipidemia and hypertension appear to be significantly protective of restenosis or thrombosis. This is probably due to the fact that the corresponding patients were treated with Statins® and antihypertensive treatment, known as protective treatments in this disease.

An analysis of systolic pressure indexes could not be performed because their measurements prior to the procedure and during follow-up were left to the discretion of the vascular physician. Finally, clinical assessment was not standardized and therefore could vary according to the medical examiner.

Our study evaluated the use of the only balloon-expandable covered stent commercially available at the time (2004), the Advanta® V12. The availability of new models of balloon-expandable covered stents, such as LifeStream® (Bard), will probably facilitate further studies.



## CONCLUSION

Despite the lack of consensus on the choice of type of stent for use in aorto-iliac occlusive disease (AIOD), the covered balloon-expandable stent used in our study appears to be a reliable, efficient and lasting solution. Morbidity and mortality are low. Primary, primary-assisted, and secondary long-term patency rates remain highly satisfactory and well above the long-term primary patency rate of bare stents, which according to the literature do not exceed 80% at one year and 60% at 5 years. Although, the mechanism of restenosis or thrombosis remains poorly understood, by achieving a true endopontage the covered stent remains promising and seems the most suitable type of stent for the treatment of AIOD. Further prospective studies with larger study populations and longer follow-up are needed to assess the benefits of this system for the prevention of in-stent restenosis compared to bare stents. The first results of the clinical trial by Bekken probably provide reliable and interesting information and will allow us to finally decide on the best choice of covered stent or bare stent in the treatment of this pathology (6).

THESE SOUTENUE PAR: **Mlle ELIE Amandine**

TITLE:

**Outcomes of covered balloon-expandable stent placement in the treatment of atherosclerotic occlusive disease at the aortic bifurcation.**

CONCLUSION:

**Objective:** The objective was to evaluate at medium and long term, the primary patency of covered stents used in first line treatment of aorto-iliac occlusive lesions and identify predictive factors of restenosis and thrombosis (FPRT).

**Methods:** Patients from a single institution with atherosclerotic occlusive disease at the aortic bifurcation treated with covered balloon expandable stent type Advanta® V12 (Maquet) in iliac arteries were enrolled between January 2004 and December 2014. It was a retrospective study but patients were followed prospectively. A surgical consultation at one month with a control Doppler ultrasound and an annual follow up by the attending vascular physician were realized. The primary objective was primary patency. The characteristics of the population of the lesion and those related to the intervention were analyzed by multivariate to identify FPRT.

**Results:** A total of 110 patients (151 limbs) were enrolled (86% of men, 41 kissing stent). The mean age was 61 years (39-86). The technical success was 100%. There were no intraoperative deaths and two postoperative deaths: one to the 13<sup>th</sup> day a severe sepsis because of urinary track infection and the other on the 5<sup>th</sup> day of acute coronary syndrome. The morbidity was low. The mean follow-up time was 51,3 months (0 ; 120). The primary patency was at 1, 2, 5 and 6 years: 94,2%, 92,1%, 90,4% and 87,3% respectively. Eight patients presented a thrombosis in a mean time of 31 months and ten stenosis in 47 months. Eleven patients (10%) required further surgery within an average of 37,8 months (0,8 ; 117,7): four iterative angioplasties and seven open

surgeries (bypass). Only the female gender was identified as a predictive factor of restenosis or thrombosis significantly.

**Conclusion:** In our experience endovascular treatment with covered stent for aorto iliac occlusive lesions is a reliable technique, efficient and sustainable. The morbi-mortality was low. In the literature, the primary patency at long-term of uncovered stents does not exceed 80 % at one year and 60 % at 5 years.

Absence of conflict of interest.

VU ET PERMIS D'IMPRIMER  
Grenoble, 05/04/16

Mr LE DOYEN

Pour la Présidente  
et par délégation  
Le Doyen de Médecine  
Pr. Jean-Paul ROMANET

Pr JP. ROMANET

LE PRESIDENT DE LA THESE



Pr JL. MAGNE

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## ANNEXES

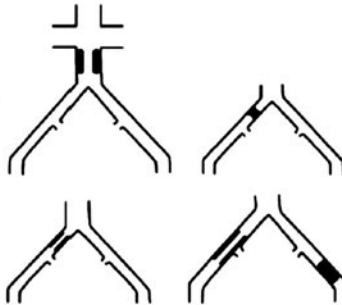
### Type A lesions

- Unilateral or bilateral stenoses of CIA
- Unilateral or bilateral single short ( $\leq 3$  cm) stenosis of EIA



### Type B lesions:

- Short ( $\leq 3$ cm) stenosis of infrarenal aorta
- Unilateral CIA occlusion
- Single or multiple stenosis totaling 3–10 cm involving the EIA not extending into the CFA
- Unilateral EIA occlusion not involving the origins of internal iliac or CFA



### Type C lesions

- Bilateral CIA occlusions
- Bilateral EIA stenoses 3–10 cm long not extending into the CFA
- Unilateral EIA stenosis extending into the CFA
- Unilateral EIA occlusion that involves the origins of internal iliac and/or CFA
- Heavily calcified unilateral EIA occlusion with or without involvement of origins of internal iliac and/or CFA



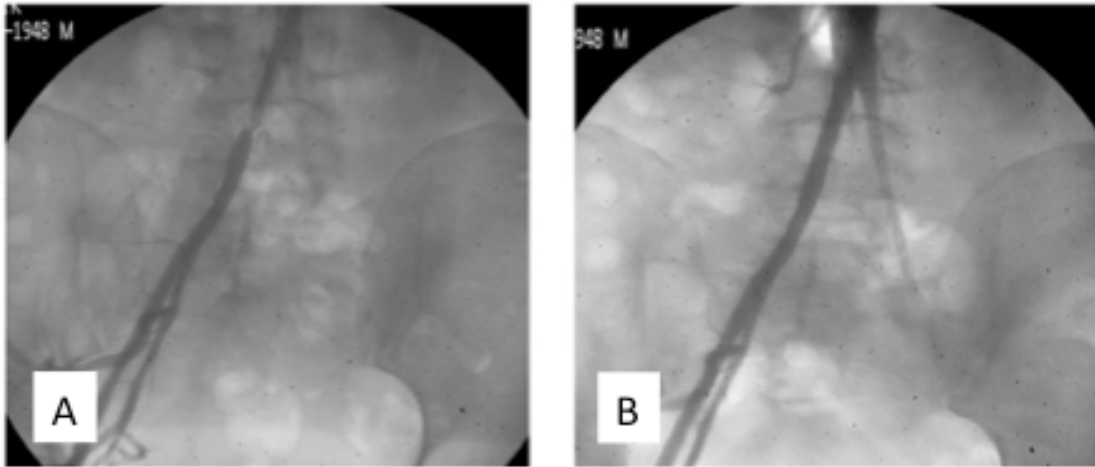
### Type D lesions

- Infra-renal aortoiliac occlusion
- Diffuse disease involving the aorta and both iliac arteries requiring treatment
- Diffuse multiple stenoses involving the unilateral CIA, EIA, and CFA
- Unilateral occlusions of both CIA and EIA
- Bilateral occlusions of EIA
- Iliac stenoses in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery

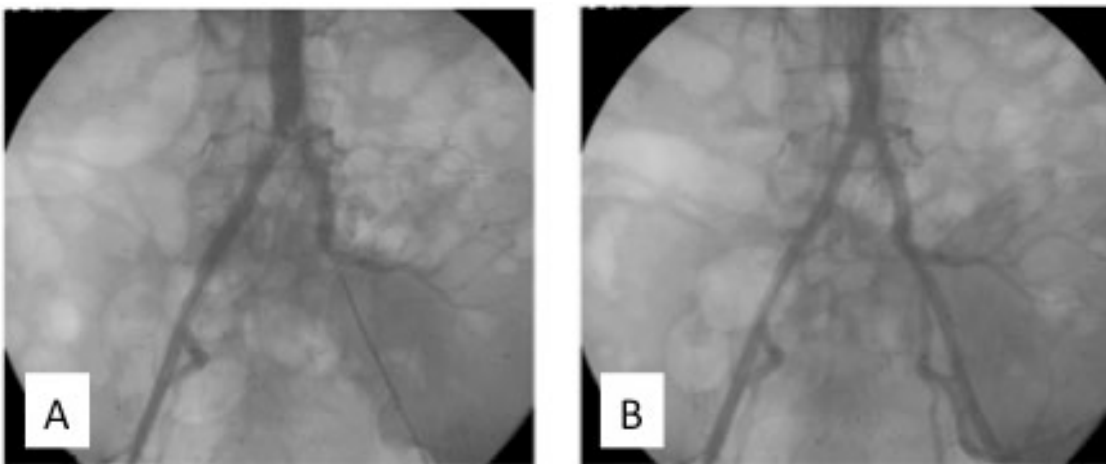


**Figure 1.** The TASC II Classification of aorto-iliac lesions.





**Figure 2.** Right common iliac stenosis , before (A) and after deployment of the stent-graft (B)



**Figure 3.** Bilateral iliac stenosis before (A) and after deployment of stents covered with kissing procedure (B).

## REMERCIEMENTS

### **A mes Maîtres en Chirurgie:**

**Au Professeur Philippe Chaffanjon:** *Votre savoir de l'anatomie et vos compétences chirurgicales sont une grande source de respect et d'admiration. Je vous remercie pour votre pédagogie et votre passion que vous savez si bien transmettre. Veuillez trouver ici le témoignage de ma sincère considération.*

**A Albéric :** *Egoïstement, je voudrais ne pas te remercier car ton départ me laisse un grand vide mais je sais que c'est pour la bonne cause... Merci pour ces 3 années travaillées à tes côtés, pour tout ce que tu m'as appris que ce soit scientifiquement et chirurgicalement. Ta technique chirurgicale, ton efficacité et ton organisation font de toi un exemple et surtout ta façon d'arriver à tout gérer : travail, mari d'une femme magnifique et père d'une si belle famille ! Et qui sait, à bientôt peut-être sur les plages de Palombaggia...*

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**Au Pr Marty Ané, au Dr Berthet et à Ludovic:** *Merci pour votre accueil. Votre service est vraiment impressionnant d'activité, enrichissant de connaissances, intense en émotions. Merci à chacun d'entre vous, vous m'avez énormément appris de par vos talents et vos qualités chirurgicales respectifs. Je suis honorée de pouvoir finir ma formation à vos côtés.*

**Au Dr Abba:** *pour toute l'estime que je te porte, tant pour tes qualités humaines que chirurgicales... Tu as presque réussi à me faire aimer la chirurgie digestive... presque...*

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**A ma famille:** *Merci à tous de m'avoir supportée pendant ces longues années d'études. Je vous dédie à tous ce travail pour vous remercier de tout ce que vous m'avez offert.*

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*temps et tu vas faire un papa extraordinaire... Notre future princesse aura de quoi être fière de son père. Merci de me permettre d'être moi, merci d'être toi, merci de toi... Mon prince, ma moitié, mon autre : Je t'aime !*

**A ma fille, ma princesse:** *A toi que j'ai tant désirée, toi qui connais au plus près chaque détail de ce travail, chaque moment de doute, de stress mais aussi de soulagement et de joie. Tu vas bientôt arriver dans notre famille et j'espère pouvoir te donner autant d'amour que j'ai reçu. Tu verras ils sont tous extra et surtout ton papa... Te sentir en moi m'aide dans mon travail et me rend plus forte. Tu nous combles déjà de bonheur... Je t'aime plus que ma vie... Tu es ma vie...*

**A mes parents:** *Une thèse de remerciements ne serait me suffire pour vous remercier...*

**A maman et Serge:** *Vous qui m'avez tout donné, merci pour tout votre amour, votre affection, votre confiance, votre patience dont vous avez toujours fait preuve malgré mon caractère... Sans vous je n'en serais pas là et je ne serais pas la femme que je suis devenue. Merci pour tous ces voyages, cette culture, cette ouverture d'esprit et ces moments de bonheurs intenses. Serge même si ce n'est pas toujours ma faute j'aime t'entendre siffler ce refrain, merci de nous avoir élevé comme tes filles... Tu ne voulais pas d'enfant et pourtant tu auras été un « pas beau » papa en or ! Maman, merci pour tous ces allers retours en P1 et pour la LCA, tu l'as toi aussi réussi la première année de médecine ! Tu es la femme la plus extraordinaire que je connaisse, ma Super Woman, tu es et resteras mon modèle !! Je vous aime...*

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*toujours auprès de moi! Vous avez été les meilleurs grands parents qu'un enfant puisse rêver d'avoir, j'espère que vous êtes fiers de moi d'où vous êtes ! Je vous aimerai toujours...*

### **A mes amis et co-internes:**

**A Jess:** *merci d'avoir toujours été là malgré la distance et merci de notre si belle amitié ! Tu me manques beaucoup ici.*

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*En Ce2, on m'a demandé quel métier je voudrais faire quand je serai grande, j'ai tout de suite répondu chirurgienne ! Et bien je ne changerais cette réponse pour rien au monde !!!*

## **SERMENT D'HIPPOCRATE**

*En présence des Maîtres de cette Faculté, de mes chers condisciples et devant l'effigie d'HIPPOCRATE,*

*Je promets et je jure d'être fidèle aux lois de l'honneur et de la probité dans l'exercice de la Médecine.*

*Je donnerai mes soins gratuitement à l'indigent et n'exigerai jamais un salaire au dessus de mon travail. Je ne participerai à aucun partage clandestin d'honoraires.*

*Admis dans l'intimité des maisons, mes yeux n'y verront pas ce qui s'y passe ; ma langue taira les secrets qui me seront confiés et mon état ne servira pas à corrompre les mœurs, ni à favoriser le crime.*

*Je ne permettrai pas que des considérations de religion, de nation, de race, de parti ou de classe sociale viennent s'interposer entre mon devoir et mon patient.*

*Je garderai le respect absolu de la vie humaine.*

*Même sous la menace, je n'admettrai pas de faire usage de mes connaissances médicales contre les lois de l'humanité.*

*Respectueux et reconnaissant envers mes Maîtres, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.*

*Que les hommes m'accordent leur estime si je suis fidèle à mes promesses. Que je sois couvert d'opprobre et méprisé de mes confrères si j'y manque.*