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RESEARCH ARTICLE

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The feasibility of the flower stenting technique for ostial lesions of the common iliac artery

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Abstract

Background and Aims: A balloon-expandable stent (BES) is generally used for ostial lesions of the common iliac artery (CIA) owing to the positional ease of stent adjustment. However, there are potential risks such as vessel dissection and perforation due to vessel overstretching during. In our hospital, we performed endovascular therapy (EVT) for CIA ostial lesions via a novel method named "the flower stenting method," using a self-expandable stent. This study aimed to analyze the efficacy and safety of this method.

Methods: This study was single-center, retrospective, and observational. We enrolled 83 patients (91 limbs) who underwent EVT with SMART stent (Cordis, Miami, Florida) for CIA ostial lesions from 2007 to 2014. The primary endpoint was the rate of freedom from target lesion revascularization (TLR) in 5 years, and the secondary endpoint was the success rate of stent placement for the CIA ostium.

Results: The average patient age was 72.3 ± 9.4 years, 71% of the patients were men, 19% were receiving hemodialysis, and 60% had diabetes. Additionally, 38% of the lesions were Trans-Atlantic Inter-Society Consensus C/D lesions, while 37% were chronic total occlusion lesions. The average lesion length was 36 ± 23 mm, and the average vessel diameter was 10.7 ± 1.4 mm. The rate of freedom from TLR was 97.3% at 5 years, and the success rate of only stent placement was 90.1%.

Conclusion: The flower stenting method leads to acceptable outcomes and is useful for accurate stent deployment.

KEYWORDS
dissection, iliac artery, stenosis, stent

1 | INTRODUCTION

Endovascular therapy (EVT) is established as the best treatment for aortoiliac lesions, and the guidelines of the European Society of Cardiology [1] indicate that EVT is the first treatment option for long-standing lesions, bilateral lesions, and short occlusive lesions and may also be considered by an experienced medical team as a treatment option for aortoiliac occlusive lesions (class IIb). Soga et al.[2] reported

that the 5-year primary patency of aortoiliac artery lesions after EVT was approximately 80%. Although the outcome of EVT for aortoiliac lesions is acceptable, it is important to discover how the procedure can be performed safely.

Aortoiliac lesions contain the ostium of the common iliac artery (CIA), and accurately deploying the stent into the ostium is important. Failure to fully cover the lesion with the stent may lead to restenosis, and the contralateral CIA, jailed by the stent strut, may cause thrombosis and disrupt intravascular access via the contralateral common femoral artery.

A balloon-expandable stent (BES) is generally used for the treatment of CIA ostial lesions owing to the positional ease of stent adjustment. However, there are risks of CIA dissection and perforation. Contrarily, self-expandable stents (SES) can be placed more safely; however, they are difficult to align. Therefore, in our hospital, we devised and practiced a novel technique that accurately deploys an SES in a CIA ostial lesion. This study was conducted to investigate the efficacy of the technique, which we called "the flower stenting method."

2 | MATERIALS AND METHODS

2.1 | Study design and patient enrollment

This was a single-center, retrospective, and observational study. We enrolled 83 patients (91 limbs) who underwent EVT via the flower stenting method using the SMART stent (Cordis Corp, Miami Lakes, Florida) for a CIA ostial lesion from April 2007 to August 2014 at our institution. The indication for EVT was consciousness of intermittent claudication and CIA stenosis confirmed by angiography or ultrasound examination.

The flowchart of this study process is shown in Figure 1. During the study period, 380 patients (399 limbs) underwent EVT for iliac artery lesions, and 94 of these patients (102 limbs) had CIA ostial lesions. Two patients (two limbs) with acute limb ischemia, two patients (two limbs) for whom the stent could not be deployed because the wire could not pass the lesion, and seven patients (seven limbs) for whom a stent other than the SMART stent was used were excluded. The remaining 83 patients (91 limbs) were included in this study. We performed intravascular ultrasound examination in all procedures.

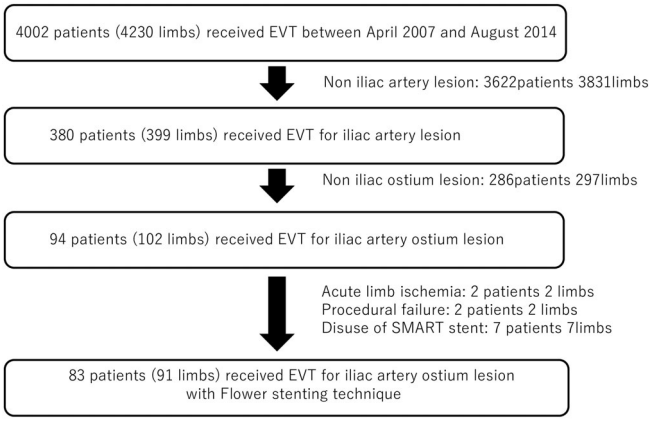


FIGURE 1 Study selection flow chart

The procedure of the flower stenting method is shown in Figures 2 and 3. Briefly, after delivering the stent, the tuning dial is turned slightly to open a distal portion of the stent in the aorta. Then, the entire catheter is slowly pulled. The place where the open stent is slightly recessed is the starting position for the deployment.

The position of this portion of the stent is confirmed by contrast with a pigtail catheter, which is inserted from the brachial artery or opposite to the femoral artery. After positioning, the remaining stent is deployed.

We named the method "the flower stenting method" because the stent is partially opened, resembling a flower.

The necessary clinical, perioperative, and demographic data were obtained through a review of hospital and physician records (Ethics Committee approval number: 20200116). This study was approved by the hospital ethics committee, and all patients involved in this study provided informed consent according to the Declaration of Helsinki.

After hospital discharge, we followed up the patients in our outpatient clinic at intervals of 1 to 3 months and conducted an interview at each visit. Moreover, ankle brachial index (ABI) assessment and ultrasound examination were performed at least once every 6 months.

The primary endpoint was the rate of freedom from target lesion revascularization (TLR) in 5 years. The secondary endpoint was the success rate of only stent placement for the CIA ostium.

2.2 | Definition

On a quantitative vascular analysis (QVA), lesions with a 5-mm distance between their proximal edge and the ostium of the CIA were defined as CIA ostial lesions. Revascularization was indicated when >50% stenosis was detected on angiography or computed tomography and when ultrasound examination revealed a >2.4% peak systolic velocity ratio on duplex scanning or a decrease of 0.2 in ABI.

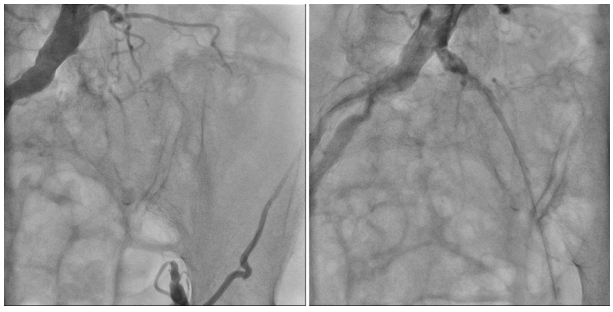


FIGURE 2 Initial angiography Angiography after guidewire passage

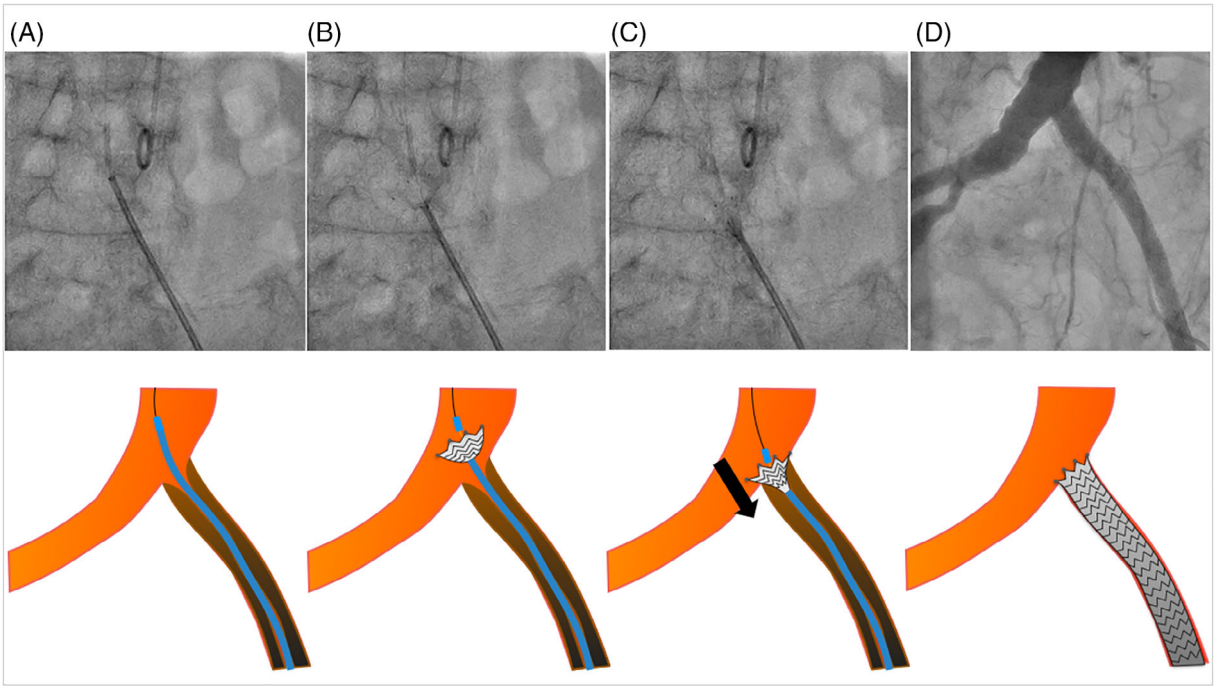


FIGURE 3 (A) Deliver the proximal edge of the stent to the terminal aorta; (B) Partially slowly open the stent in aorta; (C) Pull the catheter to the position where the partially opened stent is slightly recessed; (D) Deployment the rest of the stent

"Only stent placement" was defined as coverage of the entire lesion, with the proximal edge of the stent within 1 mm of the proximal edge of the lesion based on QVA.

2.3 | Statistical analysis

Continuous data are presented as mean ± SD or median (interquartile range, IQR), and categorical data are given as counts (percentage). For analysis of the primary outcome, the Kaplan-Meier method was used to determine CIA lesion patency during the follow-up period. All statistical analyses were performed with SPSS v.28.0 (IBM Inc., Chicago, Illinois).

3 | RESULTS

The baseline characteristics of the patients are shown in Table 1. The average age was 72 ± 9 years. Men constituted 71% of the study population; 75% of the patients had hypertension, 60% had diabetes, and 19% were receiving hemodialysis. Regarding the patients' oral medications, aspirin was prescribed for 77% of the patients and thienopyridine was prescribed for 58%. Table 2 shows the lesions and the characteristics of the procedure. The incidence of bilateral lesions was 14%. The preoperative ABI was 0.7 ± 0.2, and obstructive lesions constituted 37% of all lesions. Regarding Trans-Atlantic Inter-Society Consensus (TASC) II guidelines, TASC A or B lesions comprised 60% and TASC C or D lesions comprised 40% of all lesions in this study. The postoperative ABI was 0.9 ± 0.2, predilatation was performed in 77% of the patients, and post-dilatation was performed in all patients. The mean stent diameter was 8.7 ± 1.2 mm, and the mean stent length was 84 ± 26 mm.

TABLE 1 Baseline characteristics

	$N = 83$
Age (years)	72.3 ± 9.4
Male, n (%)	59 (71)
Body mass index, kg/m^2 ± SD	22.1 ± 3.3
Hypertension, n (%)	62 (75)
Diabetes mellitus, n (%)	50 (60)
Dyslipidemia, n (%)	42 (51)
Smoker, n (%)	17 (20)
Chronic kidney disease, n (%)	40 (48)
Hemodialysis, n (%)	16 (19)
Chronic artery disease, n (%)	46 (56)
Cerebral vascular disease, n (%)	13 (16)
Ejection fraction <40%, n (%)	9 (11)
Medication	
Aspirin, n (%)	64 (77)
Thienopyridine, n (%)	48 (58)
Cilostazol, n (%)	34 (41)
Statin, n (%)	38 (46)
ACE-Ior ARB, n (%)	29 (35)
β blocker, n (%)	17 (20)
Insulin, n (%)	14 (17)

Abbreviations: ACE-I, angiotensin-converting enzyme inhibitor; ARB,angiotensin II receptor blocker.

There was no case of dissection at the proximal edge of the stent. Data on the primary endpoint is shown in Figure 4; the rate of freedom from TLR at 5 years was 97.3%. Regarding the secondary endpoint, the success rate of only stent placement was 90.1%. Intravascular ultrasound findings after stent deployment showed that the stent covered 98.9% of the lesion. In only one case, the contralateral CIA was partially jailed, but restenosis or thrombi were not observed during the observation period.

TABLE 2 Lesion and procedure characteristics

	$N = 91$
Unilateral lesion, n (%)	78 (86)
Bilateral lesion, n (%)	13 (14)
Chronic total occlusion, n (%)	34 (37)
Lesion length, mm ± SD	36 ± 23
TASC II classification	
A or B, n (%)	55 (60)
C or D, n (%)	36 (40)
Preoperative ABI	0.7 ± 0.2
Postoperative ABI	0.9 ± 0.2
Predilatation, n (%)	70 (77)
Postdilatation, n (%)	91 (100)
Aspiration, n (%)	3 (3)
Stent diameter, mm ± SD	8.7 ± 1.2
Stent length, mm ± SD	84 ± 26
Pre-EVT quantitative vascular analysis	
Stenosis, % ± SD	78 ± 23
MLD, mm ± SD	1.7 ± 2.0
Post-EVT quantitative vascular analysis	
Stenosis, % ± SD	22 ± 13
MLD, mm ± SD	5.5 ± 1.7
Acute gain, mm ± SD	3.8 ± 2.0

Abbreviations: EVT, endovascular therapy; MLD, minimum lumen diameter.

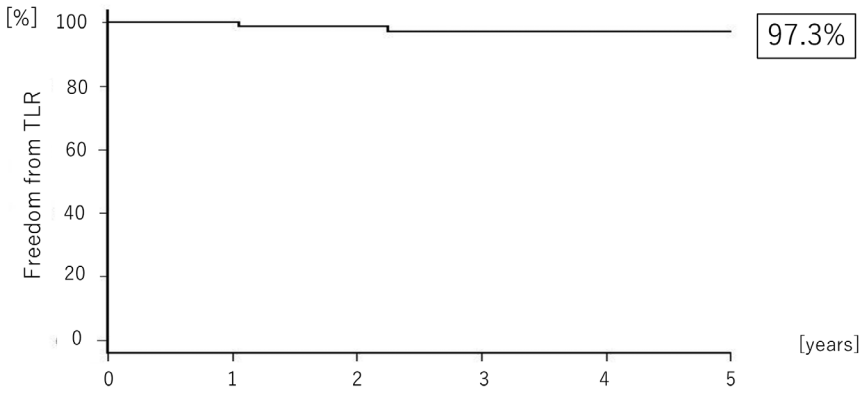
4 | DISCUSSION

EVT using stents is common for aortoiliac lesions. However, few reports have compared the outcome of BES vs that of SES or have compared outcomes depending on stent type. The randomized ICE trial revealed that SES results in lower restenosis rates and significantly lower TLR rates than BES.[3] It is considered that this is because the smaller radial force of SES[3-5] reduced the stress to the blood vessel wall and prevented neointimal hyperplasia and that the more elastic design retained the extensibility of the artery. Generally, it is considered that BES is often used because it has a stronger radial force and is easy to adjust the position of the stent. Soga et al.[2] reported that BES tended to be selected for CIA ostial lesions in Japan.

However, using BES is associated with the risk of CIA dissection or perforation. According to Krankenberg et al.,[3] 11 of 320 patients who received BES implantation for aortoiliac lesions developed dissection, perforation, major bleeding, and hematoma. Although such complications occurred in about 0.3% of the patients, which is quite infrequent, their occurrence is life-threatening. Thus, we recommend SES for better safety.

We have always performed our technique with the SMART stent. The reason for selecting this stent is that a stent design with less fluffing (Peak-to-Valle design) is effective for lesions with strong bending and for high stent expandability and stability in the long-axis direction.[6] Moreover, the micromesh stent design suppresses plaque protrusion, and the flared stent edges are nonobstructive to future blood vessel access. SMART stent implantation has been widely reported to provide acceptable outcomes for aortoiliac artery lesions.[7-9]

We believe that the SMART stent can be safely deployed without vessel dissection and the abovementioned advantages of SES can be



No.at risk	91	80	68	59	53	43
Freedom from TLR (%)	100	100	98.8	97.3	97.3	97.3

FIGURE 4 Freedom from clinically driven target lesion revascularization until 5 years after endovascular therapy

obtained. Further, we believe that our stenting method can overcome the problem of position adjustment and lead to better outcomes.

This study showed that the flower stenting method could cover CIA lesions in 98.9% of cases, and the post-EVT outcomes were acceptable. Regarding outcomes, Soga et al.[2] reported a 78% freedom rate from TLR at 5 years, and Park et al.[10] reported an 81% rate. Compared to these values, our rate of 97.3% is acceptable. In addition, there was no case of dissection in the CIA ostium, and stent placement would not hinder intravenous access for future device insertion.

A tip to note regarding this technique is to choose a stent with a length of 6 cm or more. If the length of the stent is shorter than this, the stent would not be deployed accurately because the stent deployment starts as soon as the stent is partly pulled out, and it will not be possible to perform the alignment while pulling the catheter with the stent. In addition, when deploying the stent, it is important to note the place where the edge of the stent is slightly recessed.

Another treatment for aortoiliac lesions is to use GORE VIABAHN VBX Balloon Expandable Endoprosthesis (W.L. Gore& Associates, Inc., Flagstaff, Arizona). VIABAHN VBX is the first stent graft indicated for aortoiliac lesions. According to past overseas reports,[11-13] better outcomes will be obtained with this stent than with conventional stents for both TASC C/D and TASC A/B lesions, including calcifications or bifurcations.

However, the implanted VIABAHN VBX stent is at risk of thrombotic occlusion. Although there are a few reports of iliac artery lesions, previous papers reported that lesions developed in the femoropopliteal artery within 1 year after EVT in about 10% of cases.[14-16] Moreover, these cases can have tragic complications, such as major amputation or death. However, in our study, using the definition of stent thrombosis,[17] no case of stent thrombosis was observed during the follow-up period. Previous studies[8] have reported that the incidence of stent thrombosis after SMART stent deployment for lesions in the aortoiliac artery was 1%(1/102) until 1 year after EVT. Thus, we consider the flower stenting method a safer method.

4.1 | Limitations

A limitation of this study is the relatively small study population size, which was due to its retrospective and single-center design. Additionally, to our knowledge, there are no reports on how BES can be deployed accurately for CIA ostial lesions; thus, comparison with the flower stenting method is difficult. We hope that future research will address this issue.

5 | CONCLUSION

We believe that using our flower stenting method, the SMART stent can be safely deployed without dissection and the abovementioned advantages of SES can be obtained. Further, our stenting method can overcome the problem of position adjustment and lead to better outcomes.

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CONFLICT OF INTEREST

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

AUTHOR CONTRIBUTIONS

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Formal Analysis: Kishida Toshihiko

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TRANSPARENCY STATEMENT

The lead author affirms that this manuscript submitted to Health Science Reports is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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REFERENCES

1. Aboyans V, Ricco JB, Bartelink MEL, et al. 2017 ESC guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the European Society for Vascular Surgery (ESVS). *Rev Esp Cardiol (Engl Ed)*. 2018;71:111.
2. Soga Y, Iida O, Kawasaki D, et al. Contemporary outcomes after endovascular treatment for aorto-iliac artery disease. *Circ J*. 2012;76:2697-2704.
3. Krankenberg H, Zeller T, Ingwersen M, et al. Self-expanding versus balloon-expandable stents for iliac artery occlusive disease: the randomized ICE trial. *JACC Cardiovasc Interv*. 2017;10:1694-1704.
4. Bekken JA, Vos JA, Aarts RA, de Vried JPPM, Fioole B. DISCOVER: Dutch iliac stent trial: COVERed balloon-expandable versus uncovered balloon-expandable stents in the common iliac artery: study protocol for a randomized controlled trial. *Trials*. 2012;13:215.
5. Gandini R, Fabiano S, Chiocchi M, Chiappa R, Simonetti G. Percutaneous treatment in iliac artery occlusion: long-term results. *Cardiovasc Intervent Radiol*. 2008;31:1069-1076.
6. Shirai S, Hirano K, Kobayashi N. New endovascular technique for thrombus in the non-stenting zone-the grab a clot and hold ON "(GACHON) technique": case report. *Catheter Cardiovasc Interv*. 2017;89:1087-1092.

7. Iida O, Soga Y, Takahara M, et al. Efficacy of the S.M.a.R.T control vs. other stents for aortoiliac occlusive disease in contemporary clinical practice. *J Endovasc Ther*. 2013;20:431-439.
8. Ponec D, Jaff MR, Swischuk J, et al. The Nitinol SMART stent vs Wallstent for suboptimal iliac artery angioplasty: CRISP-US trial results. *J Vasc Interv Radiol*. 2004;15:911-918.
9. Shintani Y, Soga Y, Takahara M, et al. Clinical outcomes of SMART versus Luminexx Nitinol stent implantation for aortoiliac artery disease: a propensity score-matched multicenter study. *Angiology*. 2015;66:875-881.
10. Park KB, Do YS, Kim DI, et al. The TransAtlantic InterSociety consensus (TASC) classification system in iliac arterial stent placement: long-term patency and clinical limitations. *J Vasc Inter Radiol*. 2007;18:193-201.
11. Bismuth J, Gray BH, Holden A, Metzger C, Panneton J. VB FLEX study investigators. Pivotal study of a next-generation balloon-expandable stent-graft for treatment of iliac occlusive disease. *J Endovasc Ther*. 2017;24:629-637.
12. Mwipatayi BP, Thomas S, Wong J, et al. A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease. *J Vasc Surg*. 2011;54:1561-1570.
13. Piazza M, Squizzato F, Spolverato G, et al. Outcomes of polytetrafluoroethylene-covered stent versus bare-metal stent in the primary treatment of severe iliac artery obstructive lesions. *J Vasc Surg*. 2015;62:1210-1218.
14. Bradaric C, Koppara T, Müller A, et al. Incidence and predictors of stent thrombosis after endovascular revascularization of the superficial femoral artery. *EuroIntervention*. 2019;15:e1107-e1114.
15. Ni Q, Yang S, Xue G, Zhou Z, Zhang L, Ye M. Viabahn stent graft for the endovascular treatment of occlusive lesions in the femoropopliteal artery: a retrospective cohort study with 4-year follow-up. *Ann Vasc Surg*. 2020;66:573-579.
16. Saxon RR, Chervu A, Jones PA, et al. Heparin-bonded, expanded polytetrafluoroethylene-lined stent graft in the treatment of femoropopliteal artery disease: 1-year results of the VIPER (Viabahn Endoprosthesis with heparin bioactive surface in the treatment of superficial femoral artery obstructive disease) trial. *J Vasc Interv Radiol*. 2013;24:165-174.
17. Windecker S, Meier B. Late coronary stent thrombosis. *Circulation*. 2007;116:1952-1965.

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