Performance of Open and Closed Cell Laser Cut Nitinol Stents for the Treatment of Chronic Iliofemoral Venous Outflow Obstruction in Patients Treated at a Single Centre

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WHAT THIS PAPER ADDS

This study describes the performance of open cell (OC) and closed cell (CC) laser cut nitinol dedicated venous stents in 207 patients treated for iliac vein outflow obstruction at a single centre. Patency and symptom improvement were similar at one year for 107 patients treated with CC stents and 100 patients treated with OC stents. Inflow to the stent system was found to be the most important factor influencing stent patency, however the placement of CC stents across the inguinal ligament may be associated with a greater risk of multiple re-interventions.

Objective: A number of dedicated self expanding nitinol stents have been developed for use in the venous system, with both open cell (OC) and closed cell (CC) designs available. Data comparing these different designs are lacking. The objective of this study was to evaluate outcomes in patients treated with open and closed cells for unilateral chronic iliac vein obstruction.

Methods: A single centre retrospective cohort study was conducted, including all patients treated with a dedicated nitinol venous stent between 2014 and 2019. Stent patency and details of re-interventions (including lysis, venoplasty, reinforcement, extension, arteriovenous fistula formation) were examined in the first post-operative year. Subgroup analysis described outcomes for patients treated with OC and CC stents ending above the inguinal ligament and those who required extension into the common femoral vein. Cox regression analysis was used to identify factors associated with loss of primary patency.

Results: A total of 207 patients were included (OC 100 patients, CC 107 patients). There was no significant difference between the groups for age (OC 42 years, CC 44 years); gender (OC and CC 67% female); presence of post-thrombotic lesions (OC 71%, CC 73%); stenting across the inguinal ligament (OC 58%, CC 56%), or presence of inflow disease (OC 49%, CC 47%). Primary and cumulative patency at 12 months were similar between groups (primary: OC 63%, CC 65%; cumulative: OC 93%, CC 90%). Patients with a CC stent across the inguinal ligament had a greater risk of needing multiple re-interventions at one year compared with those with an OC stent (odds ratio 2.84, 95% confidence interval [CI] 1.16 — 6.9) but overall, the only factor significantly associated with loss of primary patency was inflow vessel disease (hazard ratio 3.39, 95% CI 1.73 — 6.62, $p < .001$).

Conclusion: OC and CC dedicated nitinol venous stents were observed to perform similarly in terms of patency and symptom improvement at one year. Disease of the inflow vessels was the most important factor associated with a loss of stent patency irrespective of stent design.

Keywords: Deep vein thrombosis, Iliac vein, Post-thrombotic syndrome, Venous stent
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INTRODUCTION

Chronic venous outflow obstruction can cause significant disability and impairment to quality of life,[1—5] with associated psychological and economic burden.[6,7] Patients with disease in the proximal veins (iliac veins and inferior vena cava) are at greater risk of developing severe symptoms,[8—11] which in many cases do not respond to conservative measures with compression stockings and/or leg elevation. In recent years

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there has been a growth in the popularity of endovascular recanalisation of the iliac vein with balloon angioplasty and stenting as a treatment for patients who have failed conservative management.

The most widely used stent has been the Wallstent (Boston Scientific, MA, USA), an Elgiloy braided stent that was originally designed for use in the coronary arteries and biliary tract. Although there have been excellent outcomes reported for safety, technical, and clinical success of the procedure using the Wallstent,[12,13] there have also been reports of device related failures and adverse events with off label use of arterial stents in the iliac vein.[14] These include jailing of the stent against the vessel wall leading to contralateral thrombosis,[15] foreshortening of the stent during deployment, and stent migration.[14] Consequently, a number of self expanding nitinol stents have been designed specifically for use in the iliac vein. These can largely be divided into open cell (OC) and closed cell (CC) configurations with a broad range of sizes, with new deployment devices designed for ease of use and more precise stent placement.

The CC stent design has the theoretical benefit of improved radial resistive force leading to a better luminal aspect ratio, which some have speculated could lead to improved clinical outcomes.[16] In contrast, the OC configuration is thought to offer greater flexibility. The performance of both types of stent design have been promising in initial trials,[17–20] however data comparing these devices directly are lacking. The aim of this study was to compare outcomes in similar patients treated with different venous stent designs for unilateral chronic iliac vein obstruction by the same clinical team.

MATERIALS AND METHODS

All patients treated for chronic unilateral iliac vein outflow obstruction with OC only or CC only dedicated venous stents between 2014 and 2019 at a single tertiary referral centre were included in this retrospective cohort study. Institutional review board/ethical approval was not required at the institution, but the study was registered as an audit and service improvement project (Guy's and St Thomas' NHS Foundation Trust Hospital Audit database project no. 11903).

Procedure notes were reviewed to identify patients treated with either OC or CC stents only. Patient demographics and relevant imaging were detailed in addition to clinic letters, and details of further procedures in the first 12 post-operative months. Criteria for treatment were confirmed supra-inguinal venous outflow obstruction with >50% reduction in iliac vein diameter on either duplex ultrasound or magnetic resonance (MR) venography, Villalta score >5, and/or significant venous claudication (in the absence of formal measures to assess severity of claudication, significant was defined as symptoms of a severity sufficient to affect quality of life and for the patient to seek intervention), patient agreement to the procedure including adherence to therapeutic anticoagulation and regular surveillance duplex ultrasound scans post-procedure. In patients with significant symptoms without obstructive disease identified on MR venography or duplex, diagnostic contrast venography, and intravascular ultrasound (IVUS) were required to determine whether any obstructive pathology was present before stenting was offered. Contrast venography and IVUS were used intra-operatively to confirm the presence of an obstructive lesion and to identify appropriate stent landing zones in all patients before proceeding.

When stenting across the inguinal ligament was required, an appropriate distal landing zone above the confluence of the femoral vein (FV) and profunda femoral vein (PFV) was identified using IVUS, no stents were extended into the FV or PFV. Selected patients with extensive common femoral and inflow disease had an endophlebectomy and temporary arteriovenous fistula created to improve flow through the stent system. The decision for endophlebectomy and fistula was based on pre-operative imaging and intravascular ultrasound during the procedure (if there was no suitable landing zone identified for the stent). In some patients this was performed as a secondary procedure after loss of stent patency.

Disease of the inflow vessels (FV or PFV) was assessed pre-operatively based on pre-operative duplex ultrasound and MR venography. Significant disease was defined as >50% stenosis compared with a healthy reference vessel of one (grade 1 inflow disease) or both of the vessels (grade 2 inflow disease) observed on one or more imaging modality.

This centre's interventional technique has been described previously.[21] Stent choice was at the discretion of the treating clinician at the time of the procedure although some stents were brought to market more recently and were not available until the later part of the study. For this reason, performance of the stents is reported at 12 months post-operatively, irrespective of the total length of follow up. Post-operative anticoagulation consisted of two weeks of low molecular weight heparin, followed by warfarin for a minimum of six months. After six months patients were either switched to a direct oral anticoagulant (DOAC), continued on warfarin, or anticoagulation was discontinued based on haematology advice. Thigh length compression stockings were prescribed for a minimum of six months post-intervention. Duplex ultrasound surveillance scans were performed at 24 hours, two weeks, six weeks, six months, and 12 months post-operatively, and at additional intervals when patients presented to the department with worsening symptoms.

Re-interventions were performed for symptom recurrence, in stent stenosis >50% (in the early study period, practice changed in later years to closely observe asymptomatic in stent restenosis [ISR] rather than immediately intervene), or stent occlusion identified on duplex ultrasound. After any re-intervention, duplex surveillance scans were performed according to the same protocol, in relation to their most recent procedure. Primary patency was defined as a patent stent without any re-interventions performed. Primary assisted patency was defined as a

Table 1. Number and type of dedicated venous stents used for 207 patients treated for chronic iliac vein outflow obstruction at a single centre 2014–2019

Stent type	Stents ending above inguinal ligament		Stenting across inguinal ligament		Total	
	Patients	Stents	Patients	Stents	Patients	Stents
Closed cell (Veniti)	48	63	59	140	107	203
Open cell	42	47	58	110	100	158
Venovo	6	7	20	36	26	43
Zilver Vena	5	6	4	10	9	16
Abre	31	34	34	65	65	99

Data are presented as *n*.

patent stent with re-intervention for either symptom recurrence or in stent stenosis, and secondary patency was defined as an occluded stent that was successfully re-canalised and remained open.

Statistical analysis

Statistical analysis was undertaken using GraphPad Prism version 9.0 (GraphPad Software, San Diego, California USA) and SPSS version 27.0 (IBM Corp, Armonk NY USA). Kaplan-Meier survival analysis was used to determine primary, primary assisted, and secondary patency at 12 months for patients treated with OC and CC stents, and for patients with stents ending above the inguinal ligament *vs.* those who required stenting across it. For the purposes of this study, follow up data were analysed for the first post-operative year only. Baseline demographics were compared between subgroups using non-parametric tests. Odds ratios were calculated to compare the numbers of patients requiring multiple re-interventions in each group. Multivariable analysis of factors associated with loss of primary patency was undertaken using cox regression. The variance inflation factor (VIF) was used to assess multi-collinearity of variables included in the model, and the proportional hazards assumption was tested using a hierarchical regression strategy. A p value $< .050$ was taken to be significant.

RESULTS

Demographics

Two hundred and fifty-two patients were treated with iliac vein stenting for unilateral chronic venous outflow obstruction at a tertiary referral centre between 2014 and 2019. Of these, 207 patients met the inclusion criteria for the study, with 107 patients treated with only CC and 100 patients with only OC dedicated venous stents (Table 1). Patients treated with a combination of OC and CC stents were excluded, as were patients treated with 'hybrid design' stents containing both OC and CC components (sinus-Obliquus and sinus-Venous, Optimed, GmbH, Ettlingen, Germany). The CC stents used were the Veniti Vici® (Boston Scientific, Boston, MA, USA), and the OC stents were the Venovo® (Bard, Tempe, AZ), Zilver® Vena™ (Cook Medical, Bloomington, IN, USA), and Abre™ stent (Medtronic, NYSE: MDT). The Veniti and Zilver Vena stents were available throughout duration of the study (2014-2019) whereas the other OC stents were introduced slightly later (Venovo was used from 2016 onwards and Abre from 2017 onwards) (Supplementary Table S1).

The median age at intervention was 42 years and 67% were female. Post-thrombotic syndrome was the indication for intervention in 73% of patients with the remainder treated for non-thrombotic iliac vein lesions (NIVLs).

Table 2. Demographics of 207 patients treated with open cell (OC) or closed cell (CC) dedicated venous stents for chronic iliac vein outflow obstruction placed above or across inguinal ligament at a single centre in 2014–2019

	OC above (n = 42)	CC above (n = 48)	OC across (n = 58)	CC across (n = 59)	OC total (n = 100)	CC total (n = 107)
Age – y	38 (22–71)	41 (18–83)	47 (18–72)	47 (19–84)	42 (18–72)	44 (18–84)
Left leg	38 (90)	44 (94)	46 (78)	52 (87)	84 (84)	96 (89)
Female	29 (68)	34 (72)	36 (67)	38 (64)	65 (67)	72 (67)
Length of follow up – mo	11.5 (1–12)	12 (0.5–12)	12 (0.5–12)	12 (0.1–12)	12 (1–12)	12 (0.5–12)
Thrombophilia	13 (31)	15 (32)	17 (29)	17 (28)	30 (30)	32 (30)
NIVL	25 (59)	27 (58)	3 (6)	1 (3)	28 (29)	28 (27)
Any inflow disease	7 (18)	8 (19)	41 (69)	38 (70)	48 (48)	46 (47)
Grade 1 disease, PFV or FV >50% stenosis	7 (17)	6 (13)	28 (48)	21 (35)	35 (35)	27 (25)
Grade 2 disease, PFV and FV >50% stenosis	0 (0)	2 (4)	13 (22)	17 (28)	13 (13)	19 (18)
Number of stents per patient	1.14 ± 0.32	1.31 ± 0.5	2.07 ± 0.42	2.4 ± 0.57	1.64 ± 0.61	1.9 ± 0.76
Pre-operative Villalta score	12.5 (3–26)	14 (5–23)	14 (3–23)	13.5 (3–27)	13 (3–26)	14 (3–27)

Data are presented as *n* (%), median (range), or mean ± standard deviation. NIVL = non-thrombotic iliac vein lesion; PFV = profunda femoral vein; FV = femoral vein.

Stenting across the inguinal ligament was required in 62% of patients. There were no significant differences in baseline demographics observed between the groups (Table 2). The prevalence of inflow disease (defined as >50% stenosis in one or both of the FV or PFV identified on pre-operative duplex ultrasound or magnetic resonance imaging) was similar (OC 46% *vs.* CC 47%). The mean number of stents per patient was higher in the CC group (OC 1.65 ± 0.06 *vs.* CC 1.9 ± 0.07, $p \leq .050$), as expected given the range of stent sizes available (Veniti maximum length 120 mm, Zilver Vena 140 mm, Abre 150 mm, Venovo 160 mm). Inadequate expansion of the stent detected by intravascular ultrasound (IVUS) was observed during the index procedure for five patients (four OC, one CC), and corrected with re-lining intra-operatively. There were no incidences of stent migration or maldeployment in this cohort. The follow up index[22] was 0.87 for patients treated with OC stents and 0.94 for patients treated with CC stents.

Stent patency

Overall patency was similar for patients treated with OC and CC stents at 12 months Fig. 1). Primary patency was 63% for patients treated with OC stents, and 65% for patients treated with CC stents. Primary assisted patency was 83% (OC) and 78% (CC) and secondary patency was 93% (OC) and 90% (CC). Patients with stents that stayed above the inguinal ligament had improved patency outcomes irrespective of the stent design used (Fig. 2), with primary patency of 83% (OC) and 91% (CC), primary assisted patency of 92% (OC) and 98% (CC), and secondary patency of 100% for both OC and CC stents at 12 months. For patients who had a stent that crossed the inguinal ligament (Fig. 3), primary patency was 52% for OC stents and 44% for CC stents, primary assisted patency was 77% for OC stents and 62% for CC stents. Secondary patency was similar between groups with 89% for OC and 83% for CC.

Factors associated with loss of primary patency

Cox proportional hazards analysis was used to assess factors related to loss of primary patency. Variables of interest were included in the model providing the variance inflation factor was <2.5 and there was not significant correlation between variables. Stenting across the inguinal ligament had a strong correlation with number of stents and presence of post-thrombotic syndrome and had a VIF > 2.5, so was excluded from the model. The model was highly significant, and no variables were treated as time dependent. Inflow vessel disease was the only variable found to be associated with increased risk of loss primary patency (HR 3.39, 95% CI 1.73 − 6.62, $p < .001$) (Table 3).

Re-interventions

Sixty-six patients required a further intervention in the first 12 months after their index procedure (Table 4). The majority of these re-interventions took place in patients who had stents across the inguinal ligament. There was no significant difference between patients treated with an OC or CC stent (OC re-intervention above ligament six patients; CC four patients, $p = .50$, OC re-intervention across ligament 23 patients; CC 33 patients, $p = .20$). There was also no significant difference between the type of re-intervention that was carried out between groups.

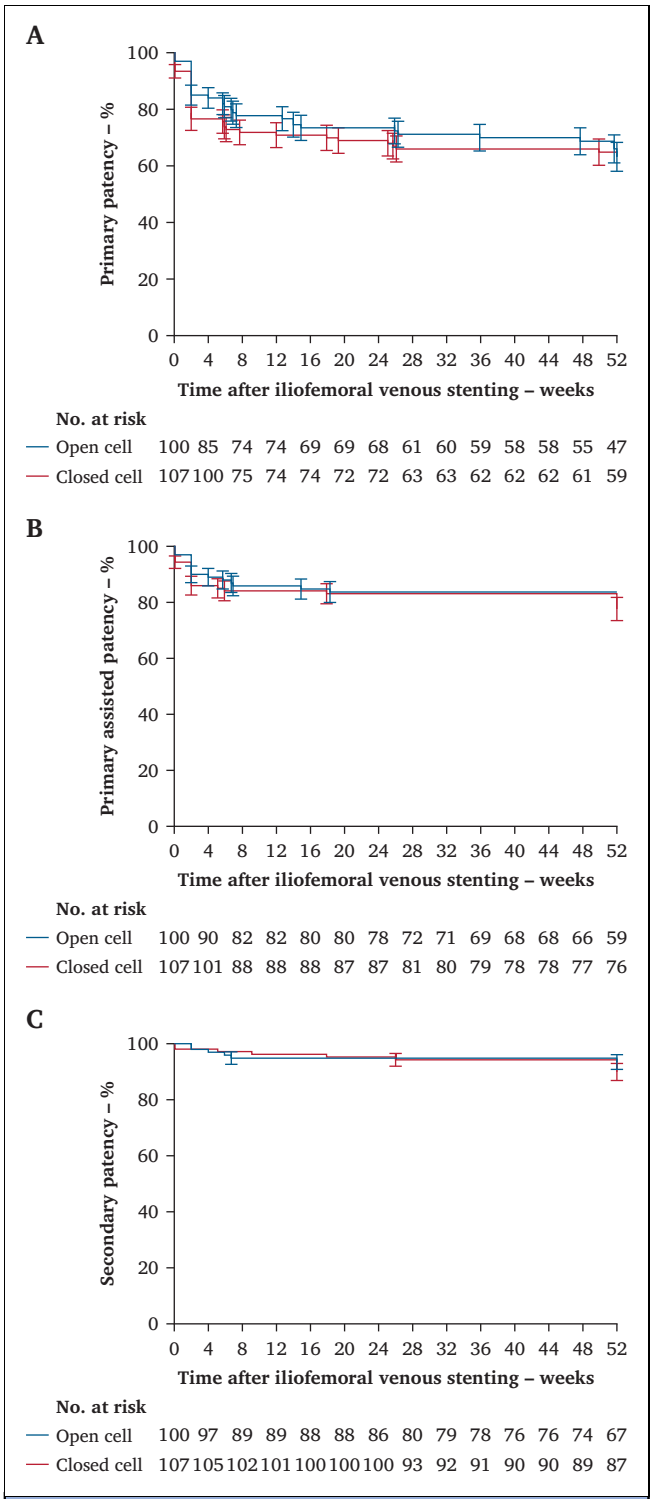

Figure 1. Cumulative Kaplan–Meier estimates of (A) primary, (B) primary assisted, and (C) secondary patency of open cell (OC) and closed cell (CC) dedicated venous stents for treatment of chronic iliofemoral outflow obstruction at 12 months.

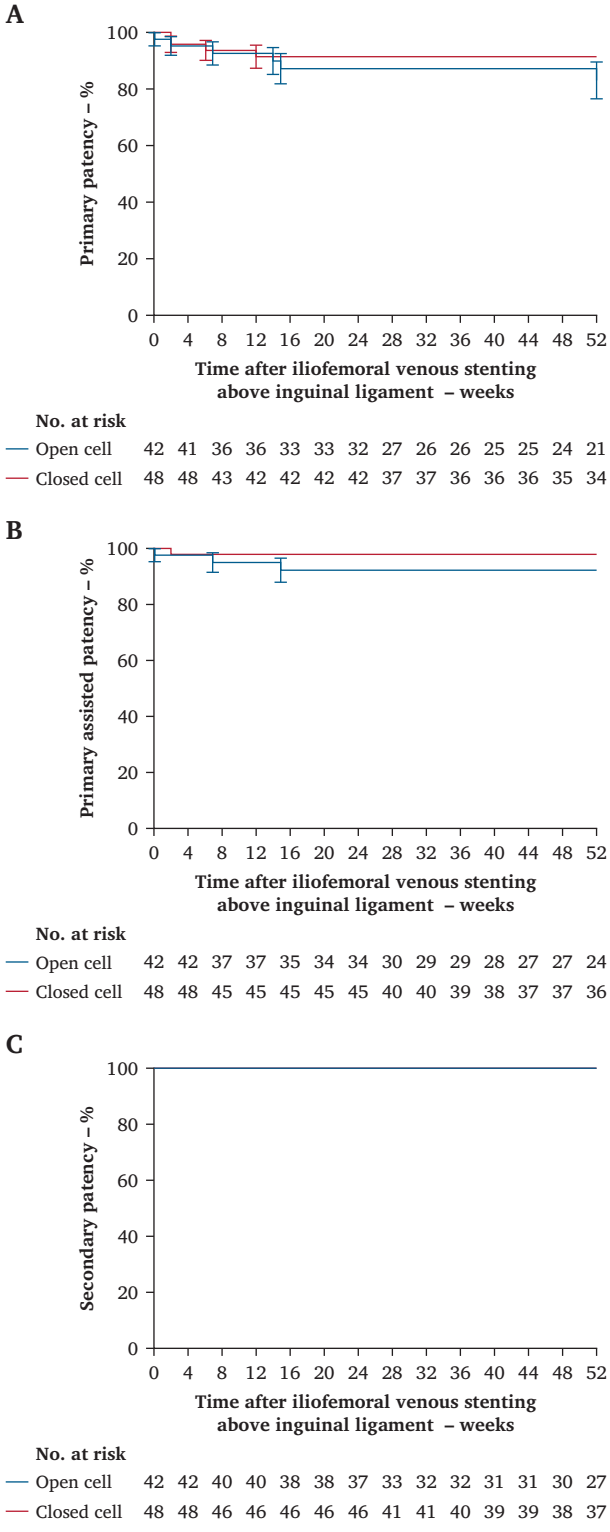

Figure 2. Cumulative Kaplan–Meier estimates of (A) primary, (B) primary assisted, and (C) secondary patency of open cell (OC) and closed cell (CC) dedicated venous stents for treatment of chronic iliofemoral outflow obstruction for patients treated with stents ending above the inguinal ligament at 12 months.

Patients treated with CC stents across the ligament were more likely to undergo multiple (>1) re-interventions than patients treated with OC stents (OR 2.84, 95% CI 1.16 — 6.9) in the first post-operative year. Relining of the stent system due to symptomatic compression or fracture was required in eight patients treated with CC stents across the ligament and in one patient with an OC stent across the ligament. The number of patients requiring balloon venoplasty or thrombolysis was similar for OC and CC stents (Table 4).

Clinical outcomes

Post-operative Villalta scores were available in 53/100 OC patients and 52/107 CC patients. There was no difference in patient demographics between those who had Villalta scores available and those who did not. Improvement from baseline Villalta score was significant for both OC and CC stents following intervention (OC baseline median Villalta score 13: interquartile range [IQR] 9, 15, post-stent score: 8, IQR 5, 13, $p = .002$; CC baseline: 13, IQR 11, 17, post-stent: 8.5 IQR 5, 12, $p < .001$) (Supplementary Fig. S1). The patients who had completed the Villalta score had a higher proportion of females (69% in completed group *vs.* 41% in the no Villalta group, $p < .001$) and patients with post-thrombotic syndrome (85% in completed group *vs.* 70% in the no Villalta group). There were no significant differences in age, rate of stenting across the inguinal ligament, presence of inflow disease or primary stent patency between those who had completed the Villalta and those who had not (Supplementary Table S2).

DISCUSSION

This study describes similar performance of the first generation OC and CC laser cut nitinol dedicated venous stents at 12 months in a single centre cohort, with satisfactory outcomes for safety and patency which are largely in keeping with initial published data on the performance of individual stents.[17–19,23–25] rates remain high, however, particularly in patients who required stenting across the inguinal ligament, and patients should be counselled appropriately about this before any intervention is carried out. Significant improvement in clinical outcomes should still be expected, however, if stent patency can be maintained.

The ideal venous stent should be predictable to deploy with sufficient radial resistive strength and crush resistance to withstand forces from the overlying iliac artery pulsations, fibrotic post-thrombotic tissue, and the compression points at the pubic ramus and inguinal ligament.[27] The stent must also have sufficient flexibility to follow the curve of the iliac vein with flexion and extension, and be durable enough to last 50 — 60 years as many of those treated are young and active. Dedicated nitinol venous stents have been developed with these factors in mind and designed to combat specific complications such as stent migration, stent

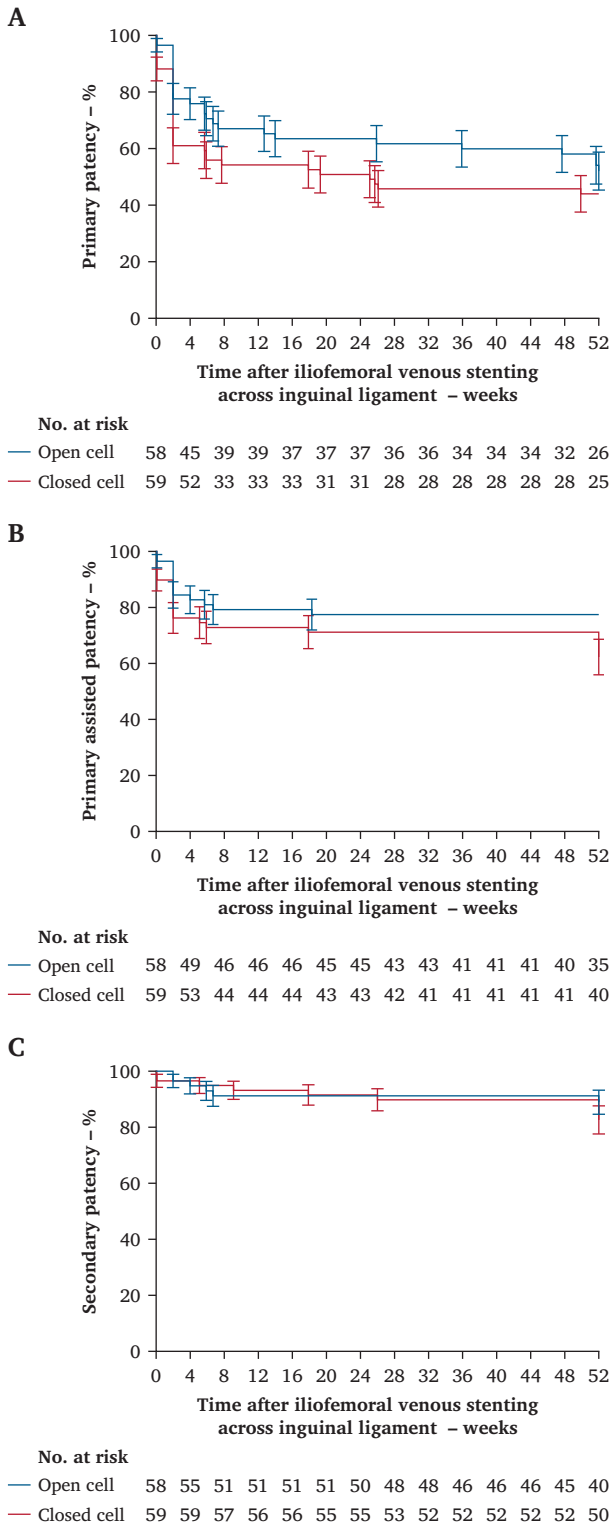

Figure 3. Cumulative Kaplan–Meier estimates of (A) primary, (B) primary assisted, and (C) secondary patency of open and closed cell dedicated venous stents for treatment of chronic iliofemoral outflow obstruction for patients treated with stents ending beneath the inguinal ligament at 12 months.

compression and kinking. A number of different venous stents have become available for use recently, and while their initial results look promising, there are inconsistencies between studies in the types of patients selected for intervention, the type of assessment and outcome measures that have been used for evaluation, variability in the operative technique, and a range of post-operative anticoagulant/antithrombotic strategies applied following intervention (and re-intervention). Direct comparison of outcomes from these studies is therefore challenging. Consensus in the assessment and selection of patients, operative techniques, appropriate tools to evaluate outcomes and clear reporting standards are needed for future health research in the area.

In this study inflow vessel disease was found to be the only factor significantly associated with loss of stent patency. The importance of inflow has been noted by a number of centres[28–33] yet there is no agreed definition of what constitutes inflow disease. A validated system to accurately classify inflow disease and risk stratify patients is required as this would allow for comparisons to be made across studies, and potentially lead to better clinical outcomes. Stenting into the FV or PFV was not undertaken in this study but with appropriate pre-operative planning to identify the dominant inflow vessel this may have the potential to reduce re-interventions by stenting across the entire obstructive lesion from "healthy to healthy",[34,35] optimising flow but avoiding the complications that arise from formation of an arteriovenous fistula. Larger studies are required to expand upon the preliminary data in this area.

Patients requiring stenting across the inguinal ligament had worse outcomes in terms of primary patency; however, secondary patency was reasonable. This difference in primary and secondary patency for stents placed across the inguinal ligament is largely due to our active duplex surveillance programme allowing for early re-intervention to prevent stent occlusion. Patients requiring stenting below the ligament usually have more extensive disease and are more likely to have disease of the inflow vessels. They are also at a higher risk of stent compression/fracture that may require a re-intervention (loss of primary patency), and although compression or fracture of the stent does not necessarily lead to stent occlusion, in some cases it will result in a recurrence of symptoms. The most common reason to re-intervene is for in stent restenosis. Raju *et al.*[36] described three types of in stent restenosis (ISR), including a "soft lesion" composed of layered thrombus because of poor inflow or outflow from the stent, which, if detected early, is easy to dilate. The second 'hard' ISR is more echogenic, difficult to dilate and more likely to recur. The third type is external compression, which may result from inadequate ballooning or recoil of previously dilated lesions and may also be influenced by stent design.

Table 3. Cox regression analysis of factors associated with loss of primary stent patency in 207 patients treated with open or closed cell dedicated venous stents for chronic iliac vein outflow obstruction at a single centre in 2014–2019

	Hazard ratio (95% CI)	*p*
Age	0.982 (0.963–1.00)	.071
Male sex	1.56 (0.972–2.5)	.066
Thrombophilia	0.678 (0.392–1.17)	.16
PTS	2.79 (0.808–9.34)	.11
Inflow disease	3.39 (1.73–6.62)	<.001
Number of stents	1.37 (.948–2.00)	.093
Procedure before 2017	1.55 (0.875–2.75)	.13

CI = confidence interval; PTS = post-thrombotic syndrome.

A recent study examining outcomes in 54 patients treated with what were considered to be more rigid stents (Sinus XL, Veniti Vici, Sinus Obliqus) to a similar matched cohort of patients treated with more flexible stents (Zilver Vena, Sinus Venous) reported significantly tapering and misalignment in the rigid stent group, and a non-significant trend for better primary patency in those treated with flexible stents.[37] This is broadly in keeping with the results of the present study, which demonstrated a trend for improved primary patency in OC stents across the ligament, with patients treated with CC stents across the inguinal ligament more likely to experience stent fracture or compression requiring a re-lining of the stent system and to require multiple re-interventions. However, it is difficult to be certain if this can be attributed to stent design alone, as surgical technique and experience have developed over time. For example, early in this centre's practice when using CC stents, if a length of >24 cm needed stenting, two 12 cm stents would be overlapped initially craniocaudally followed by a shorter stent across the ligament to the confluence of the profunda and femoral vein. The stent "overlap zone" may therefore have extended across the ligament. This centre's practice has now changed and aims to have the "overlap zone" in the curvature of the external iliac vein with a 12 cm stent — short stent — 12 cm stent configuration. In addition, indications for re-intervention have changed. Decisions to re-intervene are no longer based on the degree of in stent stenosis alone, and patients with asymptomatic stenosis are now closely observed, whereas in earlier years (2014 — 2016) 50% ISR would have been an indication for re-intervention. Techniques for re-intervention have also evolved. When relining a CC stent, rather than using another CC stent, it is now the preference of this centre to use a Wallstent due to the different properties of the braided stent upon compression. Interestingly, dedicated venous stents with a braided design have become available recently, and early results suggest that they may have benefit over laser cut nitinol stents when placed across the inguinal ligament.[38] However, they still have the same drawback as the Wallstent in terms of foreshortening and given that precise deployment is vital when stenting at the profunda and femoral vein confluence, solving one problem at the ligament may give rise to other problems elsewhere. The optimal stent design that adequately balances crush resistance, flexibility and a predictable positioning remains elusive still. Future generation of venous stents may need to be disease (PTS or NIVL) or area specific (for below the inguinal ligament or at the crossing of the right common iliac artery). Alternatively, combining a CC stent at the crossing of the artery where greater strength is required, with an OC or braided stent across the ligament may improve outcomes and should be examined in future studies. Irrespective of stent design, however, the Achilles heel of venous stenting remains poor inflow into the stent system. Strategies to assess and improve this are needed and should be a focus of future research.

Limitations

Limitations of the current study include the single centre, retrospective non-randomised design, and inadequate statistical power. No *a priori* power calculations were performed given the lack of evidence at the time and given the

Table 4. Re-interventions in the first 12 months for 207 patients treated with open cell (OC) or closed cell (CC) dedicated venous stents for chronic iliac vein outflow obstruction placed above or across inguinal ligament

	OC above (*n* = 42)		CC* above (*n* = 48)	OC across (*n* = 58)		CC* across (*n* = 59)
	Patients	Stents (*n*)	Patients	Patients	Stents (*n*)	Patients
Patients undergoing re-intervention	6	Venovo (2), Abre (3), Zilver (1)	4	23	Venovo (6), Abre (15), Zilver (3)	33
Patients with >1 re-intervention	2	Venovo(1), Abre (1)	2	9	Venovo (2), Abre (6), Zilver (1)	21
Thrombolysis	2	Venovo (1), Abre (1)	1	13	Venovo (5), Abre (7), Zilver (1)	14
Venoplasty	3	Venovo (1), Abre (3)	3	16	Venovo (1), Abre (12), Zilver (1)	20
Stent extension	4	Venovo (1), Abre (2), Zilver (1)	2	3	Abre (3), Zilver (1)	9
Stent re-lining	0		0	1	Venovo (1)	8
Re-lining at index procedure	0		0	4	Venovo (3), Zilver (1)	1
Fistula	0		0	1	Venovo (1)	2
Stent fracture	0		0	0		3

* All closed cell stents were Veniti Vici.

small differences observed in this study, a much larger sample size would be required for a trial with sufficient power to determine whether there is any statistically significant difference between the stents. This would probably only be achieved through a prospective, international, multicentre registry or randomised controlled trial. Allocation bias was inherent due to the variation in availability of stents throughout the study period, and there was no assessor blinding for determination of outcome assessments. Villalta scores were not available for all patients, with a higher proportion of female patients and PTS patients in the group with Villalta scores completed, which may have had an influence on the symptom improvement outcomes. The Vici stent was used throughout the study and although the Zilver Vena stent was also available and used during the early years of the study, the Vici was used much more frequently than the OC stents between 2014 and 2016. Increased experience with the procedure, more conservative re-intervention strategies and better identification of patients requiring stenting across the ligament would potentially have led to improved outcomes for patients treated in later years, despite consistency in the clinical team. Finally, all OC stents have been grouped together for reporting outcomes in this study and the performance of individual OC stents was not evaluated, which may be different.

Conclusion

This study describes comparable stent patency between patients treated with open cell *vs* closed cell laser cut nitinol dedicated venous stents for chronic deep venous disease in a single tertiary centre at one year. Larger prospective trials with extended follow up are required to evaluate the long term performance and durability of all the venous stents available and their impact on clinical outcomes. Irrespective of stent design, however, the inflow to the stent system appears to be the most important determinant of venous stent patency.

CONFLICT OF INTEREST

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2021.10.052.

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