Caliber-targeted reinterventional overdilation of iliac vein Wallstents

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ABSTRACT

Background: Wallstents (Boston Scientific, Marlborough, Mass) are most commonly used in iliac-caval stenting. Approximately 20% of stented limbs require reintervention to correct in-stent restenosis (ISR) or stent compression (SC). Corrective balloon dilation to rated stent caliber (isodilation) is not always successful. We investigated whether modest overdilation of the Wallstent by 2 to 4 mm (10%-20%) beyond the rated diameter would yield better mechanical clearance of ISR/SC, leading to a larger flow channel, improved conductance, reduction of peripheral venous pressure, and better clinical outcome. Outflow lumen caliber *exponentially* influences peripheral venous pressure, a key mechanism in chronic venous disease. Beyond the mechanical effects, the rationale for overdilation rests on the theory that an improvement in flow channel at the margins may yield an outsized pressure reduction and clinical improvement.

Methods: There were 274 previously stented limbs that underwent reinterventional balloon dilation for clearance of ISR/SC during a recent 3-year period. Isodilation to rated diameter of the stent was judged effective in 71 limbs (isodilated subset); 203 limbs (overdilated subset) for which initial isodilation was ineffective underwent overdilation of the resident Wallstent by 2 to 4 mm (10%-20%) beyond the original rated diameter. IVUS planimetry was used intraoperatively to calculate SC and ISR and their subsequent clearance in the two subsets. The dilated segments were observed by clinical and duplex ultrasound examination afterward. The two subsets were compared in the following outcome measures: intraprocedural efficacy in clearing ISR/SC and achieving target lumen caliber, subsequent clinical outcomes, duplex ultrasound caliber durability, and improvement in supine foot venous pressures. This is a single-center retrospective analysis of data contemporaneously entered into a time stamped electronic medical record system.

Results: The median follow-up was 18 months (range, 1-35 months). Overdilation of the stent resulted in significantly better intraoperative flow channel area improvement per intravascular ultrasound. This was reflected in significantly better clinical outcome and improvement in peripheral venous pressure in the overdilated subset. Overdilation appeared to be durable up to 20 months after intervention by duplex ultrasound monitoring.

Conclusions: Overdilation appears to be a useful technique to correct ISR/SC and to restore target lumen caliber during reinterventional correction of a resident iliac vein Wallstent. More durable caliber improvement, superior clinical outcome, and reduction in peripheral venous hypertension were noticed in overdilated stents compared with isodilation. (J Vasc Surg: Venous and Lym Dis 2019;7:184-94.)

Keywords: Wallstent overdilation; Iliac vein stent; Reinterventional overdilation; Instent restenosis; ISR

Iliac vein stenting has emerged as a new option in treating chronic venous disease (CVD) when conservative compression therapy has failed. The minimally invasive nature of the technique with an excellent safety and efficacy profile has broadened its applicability to a larger spectrum of CVD patients.[1] Wallstents (Boston Scientific, Marlborough, Mass) have been the most commonly used stent device; overall performance (patency, safety, efficacy) has been good in worldwide experience.[2] Nevertheless, some specific deficiencies are to be noted. Radial strength is not uniform but weaker near the ends. Technical performance is subpar, producing undesirable effects (compression, coning of the end, distal migration, chronic jailing of contralateral iliac) in the iliac confluence without improvised technical modifications.[3-5] Reintervention is required in about 20% of patients to correct stent malfunction, most commonly from in-stent restenosis (ISR).[4] This rarely leads to stent thrombosis but frequently compromises full stent functionality and clinical relief. This is reflected in primary patency of 20% to 30% less than primary assisted and secondary patencies that are ≥90%.[1] Stent compression (SC) by fibrous tissue of recurrent stenosis *outside* the stent is a unique cause of stent malfunction as well.[6] SC often occurs in association with ISR (Fig 1). SC appears to be more

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resistant to isodilation than ISR.[6] Clearance of ISR/SC is better with new-generation high-pressure (16 atm) balloons than with standard (6 atm) balloons.

The observed size of normal common iliac vein (CIV) is ≈16 mm, which also corresponds to the minimal caliber, calculated from flow equations, that is necessary to maintain normal peripheral pressure.[7] A prosthetic stent should be somewhat larger than native normal caliber to allow room for the inevitable buildup of some ISR with potential to reduce flow channel caliber. The optimal poststent flow channel caliber in the CIV, external iliac vein (EIV), and common femoral vein (CFV) is shown in Table I.[7] Because the Wallstent (flow channel as well) assumes a nearly circular geometry after high-pressure dilation, these areas roughly correspond to flow channel diameters as shown in Table I. We aimed to achieve these target calibers after reinterventional correction to ensure adequate stent performance (ie, decompression of the peripheral venous tree).

Venous hypertension is the basis of CVD.[8,9] Pressure reduction and clinical relief depend on conductance of the stent. Conductance is related to the *fourth power* of the stent radius per the Poiseuille equation. The magnitude of pressure effects from this exponential arrangement may not be readily appreciated. For example, a marginal increase in flow channel caliber from 14 mm to 16 mm (14%) will result in improvement in conductance (πr^4) of nearly 60% and a related improvement in pressure.

It is difficult to overdilate a fresh Wallstent beyond rated diameter without immediate recoil because it is a loosely braided spiral of free strands of wire. The caliber of the stent is derived from the spiral diameter of individual strands of wire as there are no crosslinks or hoop supports. The cells are open and unconstrained by rigid boundaries; the cells change their dimensions as the stent is expanded or contracted. However, a Wallstent that has been in place for several weeks or more can be successfully overdilated because it has been incorporated in the venous wall and the invested tissue provides a scaffold preventing recoil.[5] The Wallstent withstands overdilation up to 4 mm beyond rated diameter without fracture or disruption as evidenced in the study. Exact tolerance limits to overdilation are unknown.

With overdilation, the Wallstent foreshortens to a variable extent due to shortening of the spiral length as the spiral diameter increases. This has to be considered in interventional overdilation. Previously covered lesions at either end may become exposed, requiring extension of the hyperdilated stent.

The aim of this study was to describe results of overdilation of the resident Wallstent by 2 to 4 mm beyond its rated diameter (eg, 18-mm CIV stent dilated to 20 to 22 mm) in cases in which standard isodilation failed to correct ISR/SC and to achieve target lumen calibers. Outcome measures are the immediate (intraprocedure) efficacy of overdilation in restoring target stent lumen caliber, poststent clinical and duplex ultrasound outcome, and related peripheral venous pressure changes. These parameters are compared with the group that achieved target lumen calibers intraprocedurally by isodilation alone during the same period.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective cohort study
- **Key Findings:** A total of 274 consecutive limbs with symptomatic iliac vein in-stent restenosis or stent compression were treated with isodilation (n = 71) or overdilation (n = 203) of the stent by 2 to 4 mm. At 18 months, overdilation provided symptomatic improvement compared with isodilation; and at 20 months, overdilation resulted in improvement in iliac vein flow channel diameters ($P < .01$) and stent caliber diameters ($P < .001$). There was no improvement with isodilation compared with predilation levels.
- **Take Home Message:** Overdilation of iliac vein Wallstent by 2 to 4 mm is suggested as effective treatment of symptomatic iliac vein in-stent restenosis or stent compression.

METHODS

Terminology. Isodilation and overdilation as used in this manuscript are in reference to the rated diameter of the resident stent and not to the native caliber of the particular vein segment.

Patients. A total of 274 limbs underwent reinterventional balloon dilation of iliac vein stents during a recent 3-year period (2013-2016). In 71 limbs, isodilation was adequate (isodilation subset), but 203 limbs required overdilation (overdilation subset) in an attempt to restore optimum segmental caliber. The 274 limbs inclusive of both subsets are consecutive reinterventions during the covered period without exclusions. Prior hyperdilation was not performed in any of the limbs included in this series. The two subsets are drawn from a total of 2405 new stents placed at our institution (about 12 placed elsewhere) in the years 1997 to 2016.

This is a single-center study (three surgeons), and the procedures and follow-up adhered to a common protocol. All data shown here were contemporaneously entered into a time-stamped electronic medical record and analyzed later.

The demographics of both subsets along with Clinical, Etiology, Anatomy, and Pathophysiology classification detail at the original stent placement are shown in Table II. The indications for and technique of new stent placement have been described in detail elsewhere.[1]

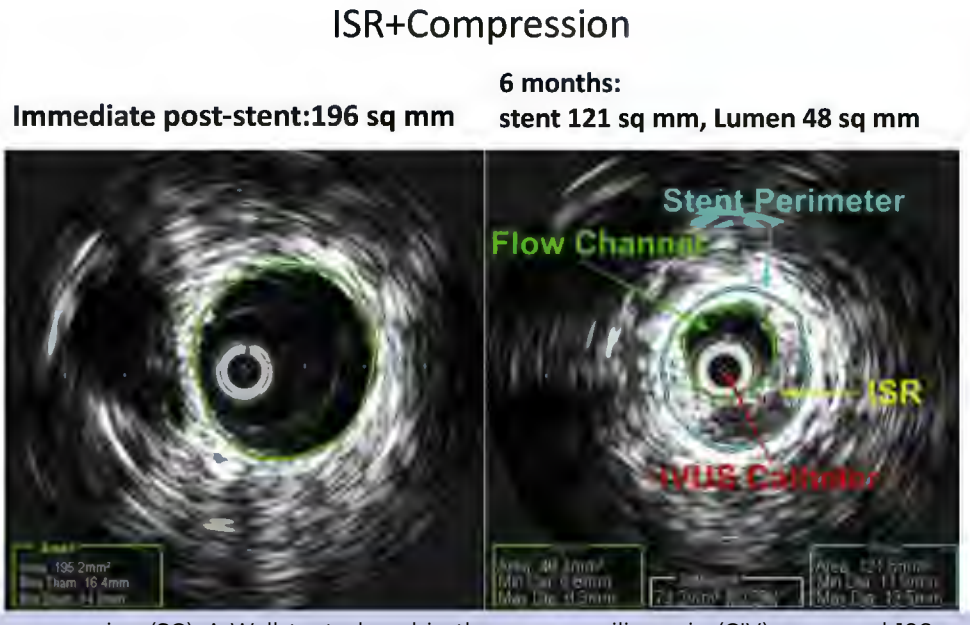

Fig 1. Stent compression (SC). A Wallstent placed in the common iliac vein (CIV) measured 196 mm^2 by intravascular ultrasound (*IVUS*) planimetry at placement (*left*). At reintervention, 6 months later, it was found to have been compressed to 121 mm^2 by irregular fibrous tissue outside the stent (*right*). The stent appears like a twisted bracelet on the IVUS image. There is some in-stent restenosis (*ISR*) as well, and the flow channel has been reduced to 48 mm^2 by combined ISR/SC, a reduction of almost 75% in a short period of time. Most SC is much more gradual in development than the example shown here.

Indications for reintervention. The primary indication for overdilation or isodilation in this series was significant residual or recurrent symptoms (pain, swelling, cellulitis, or ulcer) not responsive to compression therapy and wound care. Venous Clinical Severity Score (VCSS) detail of the limbs before reintervention is shown in the Results section. The presence of significant flow channel reduction (≥50%) by ISR/SC on duplex ultrasound was helpful in decision-making but was not determinative as intravascular ultrasound (IVUS) lumen was frequently more severe than indicated by duplex ultrasound. Stent restenoses are more symptomatic than comparable native diameter stenoses.

Informed consent was obtained from patients. Institutional Review Board permission was granted for publication of the study.

Technique. Isodilation or overdilation is performed with target caliber (4- or 6-cm length) Atlas balloons (Bard Inc, Murray Hill, NJ). The basic technique is the same. If initial isodilation fails to restore IVUS lumen caliber to target levels, overdilation of the involved segments of the resident stent by 2 to 4 mm based on caliber shortfall is performed at the same sitting. Maximum overdilation (4 mm) is generally required if the caliber shortfall from target is >15%. Overdilation beyond 4 mm is not recommended as incremental gain in stent calibers was found to be meager. There is also significant distortion of the stent's profile.

Midthigh access is obtained with an 11F sheath. This allows access to the CFV stent above the sheath. An on-table venogram is obtained, followed by IVUS examination.

The balloon is inflated to maximum rated pressure (14-16 atm). There is decay of balloon pressure as the lesion slowly "gives." Reference balloon pressure is restored and sustained until balloon pressure stabilizes without decay (usually 1-2 minutes). For technical reasons, overdilation of segments adjacent to the target segment (particularly CFV segment below EIV) is unavoidable in many instances.

In tight lesions, balloon rupture of a unique type specific to this particular model of balloon is a risk (Fig 2). The stent stack is dilated from lower to upper end to prevent the ruptured balloon's being trapped above a tight stenosis. Some tight stent lesions may be difficult to dilate, causing the balloon to slide up or down away from the lesion; repeated recentering of the balloon with slow inflation is usually successful.

Table I. Optimal caliber of iliac-femoral vein segments[a]

Vessel	Diameter, mm	Area, mm^2
CFV	12	125
EIV	14	150
CIV	16	200

CFV, Common femoral vein; *CIV,* common iliac vein; *EIV,* external iliac vein.
[a]See text for explanation.

Table II. Demographics

	Overdilation (n = 203)	Isodilation (n = 71)
Male:female	1:2	1:2
Age, years, median (range)	59 (26-89)	63 (28-86)
Operative side, left:right	1:1	1:1
Nonthrombotic:post-thrombotic	1:9	1:4
CEAP class at initial stenting	C0-2, 5%; C3, 57%; C4, 21%; C5, 5%; C6, 12%	C0-2, 2%; C3, 57%; C4, 11%; C5, 9%; C6, 21%

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology.

Overdilation of the Wallstent stack may foreshorten it, exposing original lesions at the lower or upper end (Fig 3). Stent extensions may be required to recover exposed lesions. Z-stents (Cook Medical, Bloomington, Ind) are used at the upper end to provide needed additional radial strength and to allow better cross flow at the confluence as previously described.[3] Wallstents of the same size as the balloon used for overdilation are chosen for caudal extensions; otherwise, "shelving" (incomplete apposition) at stent joints may occur.

Anticoagulation. Patients in both subsets received prophylactic low-molecular-weight heparin for 24 to 48 hours starting before the procedure. Bivalirudin 75 mg was administered during the procedure. Patients were discharged on 81 mg aspirin daily and 50 mg cilostazol twice daily. Chronic anticoagulation was used in about a third of patients for indications (recurrent thrombosis, unprovoked thrombosis, thrombophilia).

IVUS planimetry. IVUS use with intermittent fluoroscopy was integral to various stages of the procedure. ISR is readily recognized on IVUS imaging (Fig 1). It has a more variegated appearance than thrombus and lines the stent to a variable extent, encroaching on the flow channel. The stent perimeter itself appears as a dense, circular, striated band and is easily distinguishable from external structures in nonthrombotic

Fig 2. A unique type of rupture occurs in large-caliber Atlas balloons. The balloon detaches completely at the lower end from the shaft if held back forcefully from sliding "up" during balloon dilation. Any attempt to retrieve the balloon by pulling on the shaft "mushrooms" the balloon from trapping contrast material between the two layers of the balloon. Safe withdrawal through the sheath is possible if the contrast material is forced out by inflating a "buddy" balloon inserted through a separate access. Rupture can be avoided by allowing the balloon to slide up when it occurs. Slow inflation of the balloon with repeated recentering is usually successful.

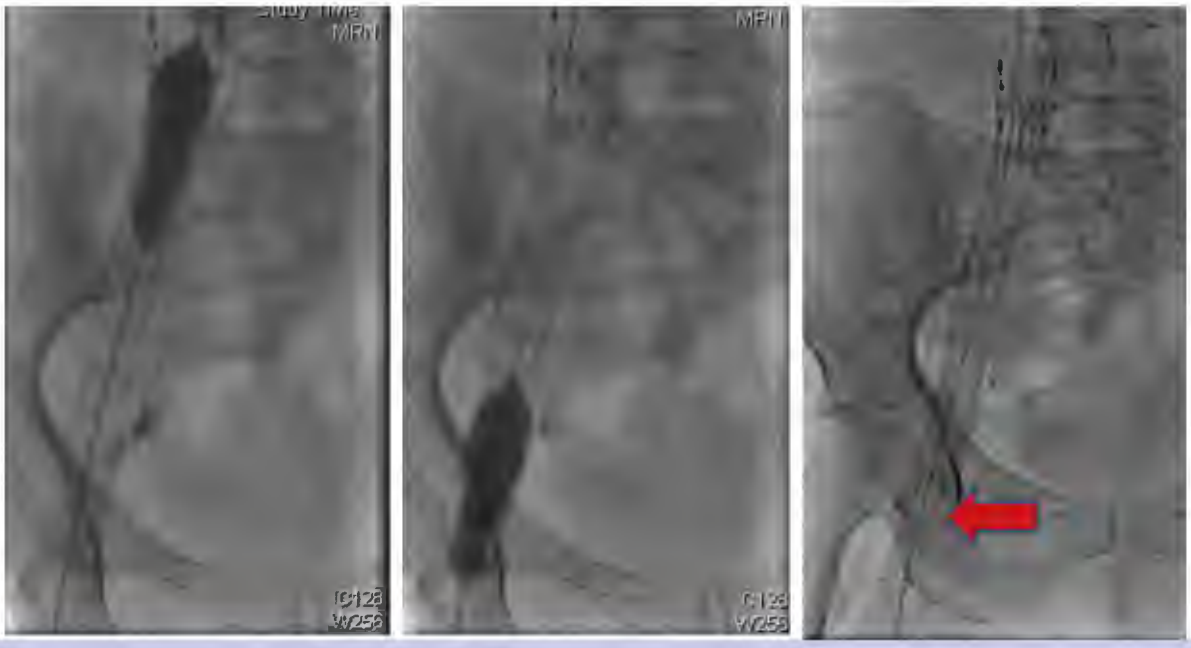

Fig 3. Foreshortening of Wallstent stack after overdilation (*left*). This exposed a previously covered stenosis below the stent as a result of foreshortening. Notice balloon waisting (*middle*). This was corrected by addition of a new Wallstent at the lower end (*arrow, right*).

disease. In post-thrombotic disease, the stent image may merge with scar tissue of similar echogenicity, and the border may be indistinct. In such instances, the innermost circular band is traced as the stent on IVUS planimetry (Fig 4).

IVUS area measurements of the stented perimeter (stented area) and the flow (flow channel area) were each obtained using the digital pen and software of the machine at the beginning and end of the procedure. The area data are presented in square millimeters. Both the flow channel area and the stented area are indexed to the desirable target area for the segment to determine respective caliber reduction. Adjacent "normal" lumen is not used as a comparator as in arterial lesions for reasons explained later.

Virtual histology. In 10 randomly selected patients, we attempted to characterize the composition of ISR using color-coded spectral analysis of IVUS backscatter signals (virtual histology). The method has been previously used and validated to study coronary artery plaques.[10,11]

A Visions PV .014P RX catheter (Volcano, San Diego, Calif) mated to the core IVUS console was used to obtain images using built-in software.

Clinical assessment. Clinical status (pain score per visual analog scale [VAS], swelling grade, and VCSS) was assessed before the intervention, at 6 weeks, and at 3- to 6-month intervals afterward. The VCSS system incorporates pain and swelling components based on subjective criteria reported by the patient. Swelling was also objectively scored by physical examination (grade 0, no swelling; grade 1, pitting; grade 2, ankle edema; grade 3, gross swelling up to knee; grade 4, swelling extending to the thigh). Swelling was considered improved if there was an improvement of at least one grade. Pain was also

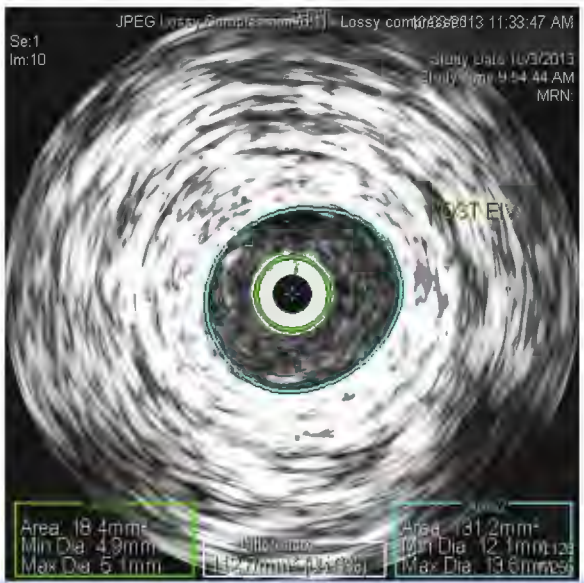

Fig 4. Persistent fibrosis in a post-thrombotic disease. The tissue outside the stent has similar echogenicity to the stent, and the border between the two is indistinct. The innermost circular band (*blue outer circle*) is traced by intravascular ultrasound (IVUS) planimetry to calculate stent caliber in such instances. The *green circle* outlines the IVUS catheter. *EIV,* External iliac vein.

Table III. In-stent restenosis (*ISR*) and stent compression (*SC*): Details of predilation in overdilated limbs (N = 203)

	Target luminal area,[a] mm²	Luminal area before overdilation, mm²	ISR component area reduction, %	Stented area before overdilation, mm², median (range)	SC area reduction, %	Overall luminal area reduction, %
CIV	200	136 (34-290)	17	170 (34-290)	15	32
EIV	150	97 (22-226)	32	146 (22-226)	3	35
CFV	125	111 (31-217)	6	118.5 (31-217)	5	11

CFV, Common femoral vein; *CIV,* common iliac vein; *EIV,* external iliac vein.
[a]These are target reference values. See text.

assessed using VAS. At least 3/10 VAS pain score was considered an improvement. Complete resolution of swelling or pain was also noted when it occurred.

Duplex ultrasound examination. Caliber of various stented vein segments was assessed by duplex ultrasound examination before reintervention and during the follow-up period at each clinic visit afterward. A color duplex ultrasound instrument (Logiq 9; GE Medical Systems, Waukesha, Wisc) was used. A 6 Hz curved probe and 9 Hz linear probe with 60-degree angle of insonation were used for the iliac-caval and femoral segments, respectively. Examination was carried out in the supine position with the ipsilateral hip elevated over a pillow. The probe was tilted from side to side to maximize the caliber of the stent image in longitudinal view. B-mode, B-flow, and color flow images were used in combination to define stent and lumen calibers at their narrowest point. Data are presented as diameter in millimeters. The coefficient of intertechnician variation for this metric in our laboratory was 9%.

Venous pressure. Peripheral venous pressure was measured through a needle in the dorsal foot vein in the supine position before and 2 to 6 months after the intervention. The coefficient of variation of pressure measurement repeated 1 to 3 weeks apart in our laboratory is 16.6%.

Statistics. Recruitment of limbs to either subset was based on procedural criteria during intervention as explained and not on statistical power estimations or random allocation. Two-tailed paired and unpaired *t*-tests were used for statistical comparisons as appropriate. Key clinical outcomes were analyzed by Wilcoxon test using cumulative data. Cumulative data are presented using Kaplan-Meier method and analyzed by Wilcoxon test for significance ($P < .05$). A commercially available statistics program (Prism software, Irvine, Calif) was used for analysis.

RESULTS

Procedural results

Stent stack extensions were performed in 72 (36%) limbs; 48 (24%) stent extensions were placed at the upper end of the stent, and 16 (8%) stent extensions were placed at the lower end of the stent. In eight (4%), a new stent was used to bridge the gap from stent separation caused by overdilation.

Intraoperative segment detail of SC, ISR, and flow channel area reduction per IVUS is shown in Tables III and IV for overdilated and isodilated limbs, respectively. The segment incidence is substantially similar. Median flow channel area reduction in both subsets ranged from 32% to 39% for CIV and EIV, and much less, 11% to 17%, for CFV. ISR is the primary culprit, and the contribution of SC in flow channel caliber reduction is less.

There was significant intraoperative improvement in flow channel area per IVUS immediately after overdilation and isodilation as well, as shown in Fig 5. Flow channel enhancement was significantly better with overdilation compared with isodilation, however, with values shown over the bracket on top of each pair of overdilation and isodilation bars. Optimum target caliber noted by the black line rectangle enclosing each bar pair was not achieved in CIV either by overdilation or isodilation; target caliber was achieved only with overdilation in EIV. Both techniques overshot the target in CFV. Overdilation of the CFV segment was unavoidable by either technique (overdilation or isodilation) while trying to

Table IV. In-stent restenosis (*ISR*) and stent compression (*SC*): Details of predilation in isodilated limbs (N = 71)

	Target luminal area,[a] mm²	Luminal area before isodilation, mm², median (range)	ISR component area reduction, %	Stented area before isodilation, mm², median (range)	SC area reduction, %	Overall luminal area reduction, %
CIV	200	132.5 (42-301)	14	160 (80-351)	20	34
EIV	150	91 (31-292)	36	145 (42-295)	3	39
CFV	125	103 (41-278)	15	122 (41-278)	2	17

CFV, Common femoral vein; *CIV,* common iliac vein; *EIV,* external iliac vein.
[a]These are target reference values. See text.

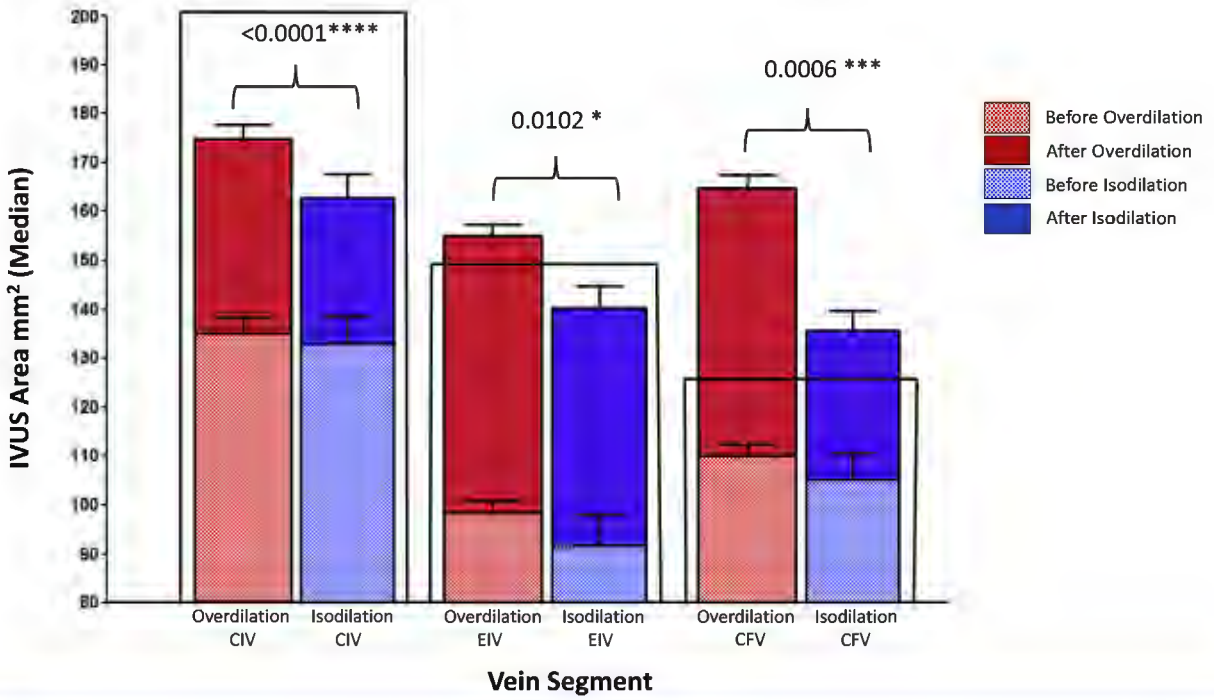

Fig 5. Intravascular ultrasound (*IVUS*) flow channel areas after overdilation (*red*; n = 203) and isodilation (*blue*; n = 71). Improvement (post vs pre) was significant (<.0001) after both overdilation and isodilation in all three segments shown. However, overdilation was significantly better than isodilation in all three segments. The relevant *P* values are shown over each pair in the bar graph: **P* ≤ .05, ****P* ≤ .001, *****P* ≤ .0001. The *black line rectangle enclosing each pair of bars* indicates the "optimum" desired caliber for the various segments. Target caliber was not achieved in the common iliac vein (*CIV*) by isodilation or even overdilation. Target caliber was achieved only by overdilation in the external iliac vein (*EIV*). Both overdilation and isodilation exceeded target in the common femoral vein (*CFV*).

dilate the EIV and CFV segments behind the inguinal ligament with balloons necessarily larger than the CFV caliber.

The median percentage improvement in flow channel area after overdilation and isodilation across all three segments was 42% (89%-478%) and 31% (62%-319%), respectively, with significantly better performance with overdilation (*P* = .0001).

The median percentage improvement in stented area (SC) after overdilation and isodilation across all three

Fig 6. Overdilation of stent with in-stent restenosis (*ISR*; *left*). The ISR was cleared with flow channel improvement (*right*). There was marginal improvement in stent caliber after overdilation. *EIV,* External iliac vein.

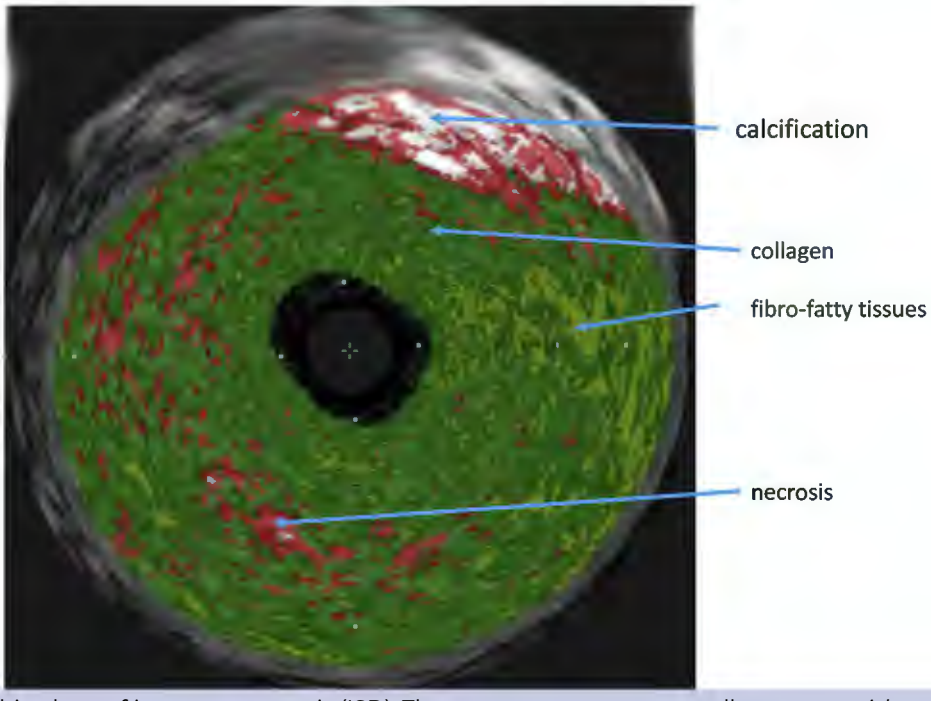

Fig 7. Virtual histology of in-stent restenosis (ISR). The *green* areas represent collagen; *greenish yellow*, fibrofatty tissues; *red*, areas of necrosis; and *white*, dense calcification. The intravascular ultrasound (IVUS) catheter can be seen in the center of the image.

segments was 15% (89%-394%) and 11% (62%-177%), respectively, with overdilation performing significantly better ($P = .0003$) toward caliber correction.

The percentage improvement after overdilation was better than isodilation for flow channel area ($P = .0001$). There was better clearance of ISR compared with correction of SC with either overdilation or isodilation (Fig 6).

Virtual histology. The composition of ISR with color spectrometry is primarily collagen with fatty elements and areas of necrosis (Fig 7). Areas of calcification can be seen in some images. The presence of early thrombus could not be determined as current virtual histology technology is unable to detect it.[11]

Clinical results

Median follow-up was 18 months (1-35 months). Data at one or more scheduled follow-up visits was available in 98% of the overdilation subset and in 88% of the isodilation subset.

Complications of isodilation and overdilation. There was no death. Access site hematoma occurred in 6% of limbs. Postoperative back pain of limited duration occurred in about 25% of patients in both subsets; all were controlled by routine analgesics without requiring readmission. Back pain incidence was not estimated to be different between the subsets, but precise data on this score were not kept. Postoperative deep venous thrombosis (<30 days) occurred in three (1%) patients. Stent occlusion occurred in five (2.5%) limbs after overdilation. All were successfully reopened by balloon maceration of the thrombus. There was no clinically detectable pulmonary embolism.

Clinical outcome. Overdilation resulted in significant clinical improvement in VCSS scores, and VAS pain

Table V. Clinical outcomes[a] after overdilation (n = 197) and isodilation (n = 67)

	Before overdilation	After overdilation	Before isodilation	After isodilation
Follow-up, months, median	–	18 (1-35)	–	18 (1-35)
VCSS	6.3 (±3.3)	5.1 (±3.6)**	7.0 (±3.6)	5.1 (±3.46)**
VCSS swelling	2.5 (±1.0)	1.7 (±1.3)**	2.3 (±1.2)	1.9 (±1.4)
VAS pain score (1-10)	4.9 (±3.4)	3.1 (±3.3)**	4.9 (±3.6)	4.6 (±3.3)
Active ulceration	16%	5%*	22%	17%

VAS, Visual analog scale; *VCSS*, Venous Clinical Severity Score.
*$P \leq .01$, **$P \leq .001$.
[a]At last follow-up.

Table VI. Cumulative symptom improvement (Kaplan-Meier method) at 18 months

	Partial pain improvement,[a] %	Complete pain relief, %	Partial swelling improvement,[b] %	Complete swelling relief, %
Overdilation (n = 203)	62**	58*	52*	46
Isodilation (n = 71)	46	42	39	38

*$P \leq .05$, **$P \leq .01$ (comparing overdilation vs isodilation).
[a]Visual analog scale (VAS) score for pain ≥3/10.
[b]Swelling improvement of at least one grade.

scores, as shown in Table V. Isodilation showed significant clinical improvement in total VCSS but not in individual swelling or pain scores, as shown in Table V. After overdilation, 21 of 31 (67%) ulcers healed, whereas only 3 of 13 (23%) ulcers healed after isodilation ($P = .008$).

Significant improvement in objective swelling by examination and pain per VAS scale also occurred and was durable for up to a median of 18 months after overdilation, but this was not the case with isodilation, as shown in Table VI (cumulative data, Kaplan-Meyer method).

Duplex ultrasound outcome. Duplex ultrasound caliber data in limbs of both subsets at 20 months after intervention are presented in Table VII. Flow channel and stent diameters in the CIV and EIV remained significantly improved compared with before intervention in the overdilated subset. There was no change in the CFV diameters.

No change occurred in CIV and EIV flow channel and stent diameters in the isodilated subset from preintervention levels at 20 months. CFV stent diameter was significantly reduced at 20 months in the isodilated subset.

Venous pressure. Peripheral venous pressure measurements were started in the last half of the study period. Both before and after stent measurements were available in about a quarter of each subset. Significant improvement in supine foot venous pressure occurred after overdilation but not after isodilation as shown in Table VIII.

DISCUSSION

Target calibers for iliac-femoral outflow. Because the lower limb inflow is a fixed fraction of cardiac index (≈12%), the minimal caliber of an iliac vein stent that would result in a normal venous pressure (≤12 mm Hg) can be calculated by hemodynamic equations.[7,9,12] Optimal sizes for CIV, EIV, and CFV are shown in Table I. The values correspond to IVUS measurements observed in normal (nonstenotic) iliac-femoral vein segments. Flow channel and stent caliber values presented here are therefore indexed to these reference values.

In large arteries, perfusion is not hampered until a stenotic lesion exceeds 60% to 70% ("critical" threshold). This is due to "autoregulation" resulting in peripheral vasodilation that offsets flow effects of lesser stenosis. There is no such autoregulation on the venous side, and there is no critical threshold. As little as 13% venous caliber reduction has been shown to elevate peripheral pressure in experimental simulations.[13]

The pressure gradient across iliac venous stenoses is generally small (<3 mm Hg) because of lower ambient pressures. It is often drowned in the "noise" of cardiopulmonary phasic variations of 2 to 5 mm Hg. Stenotic pressure gradients are further masked by contralateral iliac flow and the intra-abdominal pressure.[13] Pressure gradients even with inflow augmentation by papaverine or exercise have low diagnostic sensitivity in this location.[14,15]

Table VII. Duplex ultrasound caliber at 20 months after overdilation and isodilation

	Overdilation (n = 61)			
	Flow channel diameter, mm		Stent caliber diameter, mm	
Vessel	Before overdilation	After 20 months	Before overdilation	After 20 months
CIV	10.6 (3-17)	14 (8-19)***	14 (9-22)	16 (12-21)***
EIV	9 (4-15)	10 (6-17)**	13 (9-19)	16 (12-23)***
CFV	11 (4-17.9)	11 (6-18)	13 (9-19)	13 (6-19)
	Isodilation (n = 27)			
Vessel	Before isodilation	After 20 months	Before isodilation	After 20 months
CIV	11 (5-15.9)	11 (4-18)	14.5 (13-19)	16 (10-21)
EIV	9 (5-14.7)	10 (5-14)	13.5 (12-17)	14.9 (11-20)
CFV	11 (3-16)	11 (7-15)	14 (12-15)	12 (9-15)* ↓

CFV, Common femoral vein; *CIV,* common iliac vein; *EIV,* external iliac vein.
*$P \leq .05$, **$P \leq .01$, ***$P \leq .001$ (comparing before and after).
↓ Decrease in diameter.

Table VIII. Foot venous pressure improvement after overdilation and isodilation

	Foot venous pressure, mm Hg, median (range)		*P* value
	Before	After	
Overdilation (n = 41)	13 (4-22)	9.5 (3-19)	.016*
Isodilation (n = 18)	15.5 (6-29)	12 (8-19)	.185

*$P \leq .05$ (before vs after).

Hemodynamic impact of ISR/SC. The median IVUS stenosis due to ISR/SC in symptomatic stented limbs is milder (35%-39% in this material) than that encountered in native stenosis (typically ≈60%).[1] The critical dimensions of a stenosis that determine its hemodynamic severity are the radius and length, the radius entering in the Poiseuille equation in the fourth power, the length in the first power (r^4/l). For this reason, length is not a factor in focal stenosis, only the radius. Length does become a factor if the lesion is long. Average length of the stent stack in this material is ≈15 cm, which becomes a significant factor in resistance and related peripheral pressure rise. To give a theoretical example, a 25% ISR/SC diameter stenosis in a 16-mm × 15-cm iliac stent will roughly offer the same resistance as a 1-cm-long native CIV diameter stenosis of 63%. In addition, a long stent tends to block collateral flow, a mitigating factor in native stenosis.

ISR and SC. Currently, the majority of reinterventions after Wallstent placement in our practice are related to development of ISR/SC, although the incidence and severity of this lesion are less than in the arterial system.[16] The precise nature of venous ISR is unknown, but it is probably different from arterial ISR. There is a "soft" variety that develops early after fresh stenting and clears easily with balloon isodilation or sometimes with anticoagulation alone.[4] This is likely thrombus lining of freshly placed stent. It may be related to poor inflow. The limbs described in this report are mostly of the chronic "hard" variety made up of collagen (Fig 7) more resistant to balloon dilation than the soft variety. Virtual histology data obtained in a small number of selected limbs offer a valuable clue to the likely composition of this lesion.

A less well known cause of Wallstent malfunction is SC. This is a unique complication not seen in arterial stent deployments.[6] The pathology and etiology of SC are obscure. Likely promotional factors include the collagen proliferation in the post-thrombotic response possibly restimulated by balloon or stent injury.[17] This type of malfunction is difficult to recognize on venography (Fig 8). SC is more resistant to balloon dilation than ISR as noted in this analysis.

Because there is no satisfactory treatment at present directed at the root cause of ISR/SC, we are left with measures that might minimize their impact if they develop and degrade clinical outcome after stent placement. Importantly, stents of adequate caliber should be used and undersized stents should be avoided. A small-caliber stent with ISR/SC is an iatrogenic stenosis that is almost impossible to correct.

We currently place either an 18- or 20-mm-diameter Wallstent in the CIV, depending on body size. This slight oversizing allows some degree of protection to flow channel caliber from encroachment by ISR/SC. Balloon sizes of 16 to 20 mm are used as needed to ensure that completion planimetry values meet the minimums. The larger balloons may be required particularly in post-thrombotic limbs to achieve target lumen size. With this approach, we have found that completion calibers fall within ±10% of the recommended thresholds.

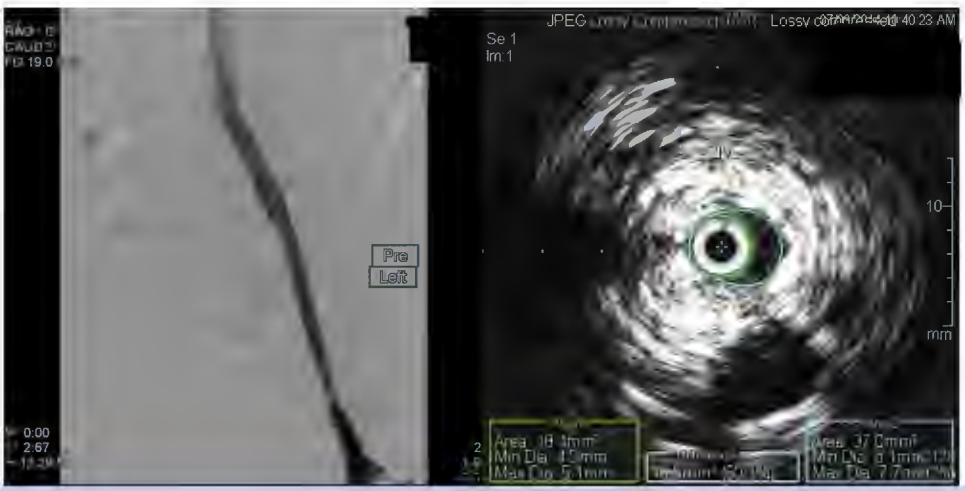

Fig 8. Stent compression (SC). The venogram appears deceptively "normal" because of lack of internal scale (*left*). Severe SC is readily apparent on intravascular ultrasound (IVUS) examination (*right*). IVUS area measurement is 37 mm^2 in the common iliac vein (*CIV*) segment (optimal area is 200 mm^2), representing an area reduction of 81%.

CONCLUSIONS

Overdilation of a resident Wallstent appears to be a useful reinterventional technique to correct ISR/SC if it develops and is resistant to standard balloon techniques currently used.

AUTHOR CONTRIBUTIONS

Conception and design: SR
Analysis and interpretation: SR, AK, WB, CM, AJ
Data collection: SR, AK, WB, CM, AJ
Writing the article: SR, AK, WB, CM
Critical revision of the article: SR, AJ
Final approval of the article: SR, AK, WB, CM, AJ
Statistical analysis: SR, AK, WB, CM
Obtained funding: SR
Overall responsibility: SR

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