Intravascular Lithotripsy in Calcified Peripheral Lesions: Single-Center JEN-Experience

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Abstract

Peripheral artery disease (PAD) shows increasing need for revascularization therapy. Interventional success in calcified lesions is limited. Here, intravascular lithotripsy (IVL), modifying intimal and medial calcium, is a promising treatment approach. A single-center, prospective all-comers registry for patients undergoing peripheral IVL was established to examine treatment success in PAD with severe vessel calcification. Periprocedural safety events as well as short-term and intermediate follow-up clinical data were evaluated. Between December 2018 and January 2021 all consecutive patients receiving peripheral lithotripsy at our center were analyzed. Clinical and angiographic data were evaluated. Angiographic images were analyzed using a semiautomatic software for quantitative vessel analysis. Eighty-five lesions in 61 limbs were treated with IVL in 51 patients presenting with Rutherford classes 2 to 5. Most lesions (68%) were localized in the superficial femoral artery. Mean calcified lesion length was 102.5 mm (10–390 mm), with a median peripheral arterial calcium score of 3, indicating a highly calcified status. In 58% of the patients, IVL was used as a stand-alone therapy. IVL resulted in a mean acute luminal gain of 2.6 ± 0.9 mm, resulting in stenosis reduction by $42.1 \pm 15\%$. Mean ankle brachial index (ABI) improved significantly from 0.6 to 0.8 ($p < 0.0001$) on day 1 after the intervention and remained stable at 6 months. This large real-world data of peripheral IVL reports compelling safety in a complex patient cohort. For the first time, clinical follow-up data demonstrated a sustained significant improvement in ABI after 6 months.

Keywords
- intravascular lithotripsy
- peripheral artery disease
- calcification
- single-center experience
- ankle brachial index

Peripheral arterial disease (PAD) is a common and globally increasing problem. As of 2015, the estimated prevalence of PAD is over 230 million worldwide.[1]

In recent years, minimal invasive approaches and conservative medical therapy have been developed to treat intravascular lesions and lower vascular risk factors, respectively. As a result of those successful approaches, a major decrease of required vascular surgeries could be observed.[2]

However, interventional treatment of severely calcified lesions is particularly challenging. Vascular calcification, which becomes more prevalent with higher age, renal failure, and diabetes mellitus,[3] is associated with higher rate of dissections,[4] restenosis,[5] poor balloon expansion,[6] general worse clinical outcome,[7] and more frequent

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amputations.[8,9] Considering below the knee (BTK) lesions, early recoil of heavily calcified lesions has been reported.[10]

The use of drug-coated balloons (DCBs) has its shortcomings in calcified lesions. Its mechanism of action is to deliver an antiproliferative drug to the intima-media complex, where the balloon dilatation induces hyperproliferation of smooth muscle cells from the media. The medication is not able to penetrate the target layer due to calcium deposits.[11] Therefore, dedicated vessel preparation of severely calcified lesions is of utmost importance. Numerous devices using different approaches have been developed. High-pressure noncompliant balloons achieve a higher expansion in stenoses difficult to dilate. Scoring balloons gain additional expansion by creating indentations in the plaques[12] with a nylon or nitinol wire mounted on the surface of a noncompliant balloon. This technique frequently provides success but has its limitations in circumferentially calcified vessels. However, published results on scoring balloons showed higher rates of vessel occlusions.[12,13] Further, atherectomy systems, including rotational, orbital, laser, and directional methods, were investigated, for example, in REALITY and DEFINITVE AR study programs,[14,15] showing higher rates of occlusion, vessel dissection, perforation, and distal embolization[12,13] and requirement of further adjunctive therapy.[16,17]

In recent years, intravascular lithotripsy (IVL), using a new approach adopted from urological lithotripsy, has emerged as treatment option for PAD patients with severe calcification.[18] Electrohydraulic-generated sonic waves pass through soft tissue and interact with highly calcified structures. IVL has been used on peripheral, coronary, and carotid arteries before.[19–21] At the target lesion, the IVL balloon is inflated with low pressure. Then, shockwaves with a mechanical energy equivalent to 50 atmospheres of a conventional angioplasty balloon spread through the soft tissues.[22] Thus, IVL can crack calcified plaques within the intima-media complex and help to establish vasomotion without destruction of the vessel layers.

IVL has presented reliable results in the DISRUPT-PAD trial programs, cofounded by the developer of the IVL device.[23–26] DISRUPT-II looked primarily into the safety of IVL procedures, restricted to the superficial femoral artery (SFA), popliteal vessels, and IVL therapy only. It presented clinical data of 60 patients from 8 clinical sites.[25] The latest DISRUPT-PAD-III comprises a randomized trial (further abbreviated as DISRUPT-III-RT), which is restricted to superficial femoral and popliteal arteries as well as usage of DCB after IVL (153 IVL subjects on 18 sites), and an observational study (DISRUPT-III-OS), which investigates IVL in multilevel PAD without restriction to adjunctive therapy and thus reflecting real-life setting (200 patients on 18 sites). Both credit short-term safety of IVL[23] and showed superiority over percutaneous transluminal angioplasty (PTA) prior to DCB stenting.[26] Full clinical data sets are still to be published. In addition to the DISRUPT-PAD trial, there are two other single-center experiences on IVL with less than 10 patients.[27,28]

Currently, real-world data of IVL including clinical follow-up in this difficult to treat cohort are lacking. Therefore, this study presents the IVL experience and intermediate clinical follow-up in a single-center all-comers registry.

Methods

Patient Recruitment and Follow-Up

The angiological workup of PAD patients included measurement of resting ankle brachial index (ABI), standardized treadmill test (with a slope of 12% and a speed of 3.2 km/h), a post-treadmill ABI measurement, and duplex ultrasound. Additionally, main cardiovascular risk factors: smoking, diabetes mellitus, arterial hypertension, and hyperlipidemia were documented. Medical treatment was then initiated or optimized according to recent guidelines.[29–32] An indication for invasive angiography was set if the patients had limiting claudication or chronic limb-threatening ischemia (Rutherford category 4–6). After PAD was confirmed, claudicants were advised to perform exercise training according to current guidelines.[29]

Postinterventional medical therapy included aspirin and clopidogrel for 4 weeks. However, patients with indication for (oral) anticoagulation received additional clopidogrel for 4 weeks.[29] Since 2020, eligible patients were set on aspirin and low dose rivaroxaban (2×2.5 mg) since they have a low bleeding risk according to the results of the Voyager trial.[33] On the postinterventional day, resting ABI was performed and the mean value between dorsalis pedis and posterior tibial artery was calculated. Follow-up measurements consisting of ABI and treadmill test were scheduled every 6 months after IVL procedure. The trial was approved by local ethics review boards.

Intervention and IVL Procedure

Three experienced investigators performed all interventions. The access was gained either transfemoral or via left brachial artery. We applied IVL in patients with severe calcification and long, multilevel peripheral stenoses. Fluoroscopic evidence of calcification on parallel sides of the vessel was defined as threshold for an IVL indication. Calcified lesions were crossed with a 0.014-inch wire, predilatation with an undersized balloon was at the discretion of the investigator. In cases of chronic total occlusions (CTOs), these were crossed with a 0.018 or 0.035 wire. The IVL device was used according to the manufacturer's instructions and as previously described.[23] The appropriate diameter of the IVL catheter had a 1.1 ratio to the distal reference vessel diameter (RVD). The IVL balloon was advanced across the lesion, connected with the IVL generator, and inflated to 4 atm using a mixed contrast and saline solution to achieve balloon-vessel wall apposition. Lithotripsy was applied in 30-pulse cycles, while the balloon pressure was kept at 4 atm. In long calcified lesions a 10-mm overlap with the former treated area was maintained. Any adjunctive therapy, such as repeated IVL, postdilation, DCB, and/or stent implantation, was performed if necessary at the discretion of the investigator.

Assessment of Lesion Calcification

The presence and grading of lesion calcification was performed using the native fluoroscopy image series, according to the peripheral artery calcification scoring system (PACSS) criteria.[6]

Quantitative Vessel Analysis

Peripheral arterial lesions were quantified using the *QVA 8.0* module within the Medis Suite software (Version 3.2.60.4), Medis Imaging Systems, Netherlands.[34] Quantification was performed retrospectively using the two-dimensional single-plain image series. The lesions were measured before and after intervention according to the steps demonstrated in ►**Fig. 1**.

Statistical Analysis

Statistical analyses were performed using IBM SPSS 27 and Prism 7.0a by GraphPad, Inc. Discrete variables are presented

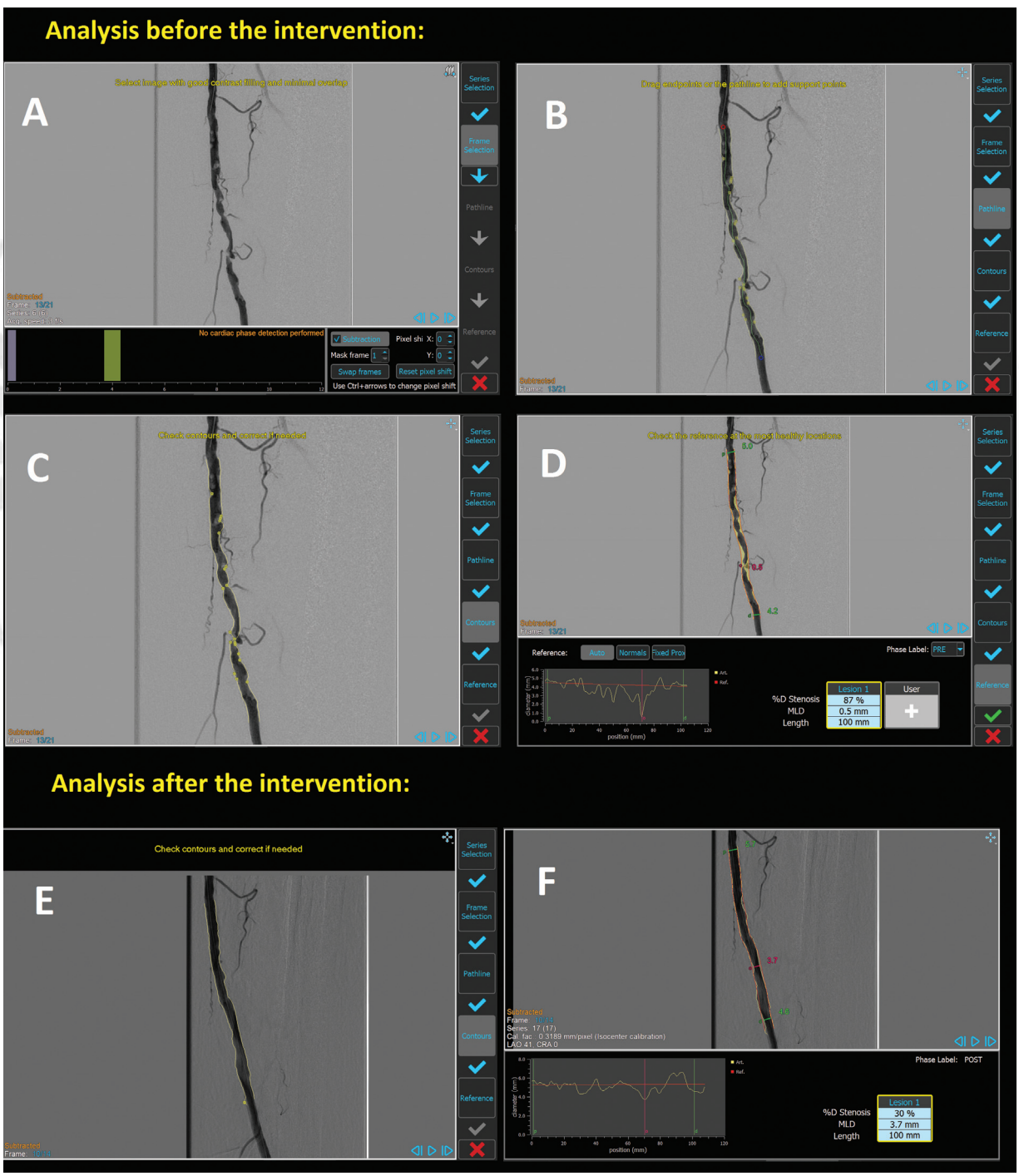

Fig. 1 Quantitative vessel analysis (QVA) before and after the procedure. (**A**) Selecting the optimal frame. (**B**) Setting the endpoints of the lesion. (**C**) Correction of the vessel contours. (**D**) Checking the reference points and lesion analysis. (**E**) Performing the same steps after the intervention. (**F**) Lesion analysis.

Table 1 Patient characteristics

	$n = 51$[a]
Age (y)	71 ± 8.7
Gender	
Male	40 (78%)
Female	11 (22%)
Cardiovascular risk factors	
Hypertension	50 (98%)
Diabetes mellitus	41 (80%)
Hyperlipidemia	38 (75%)
Smoking (current or former)	34 (67%)
Renal insufficiency (GFR < 60 mL/min)	24 (47%)
Hemodialysis	3 (6%)
Baseline measurements	
Resting ABI[b]	0.6 ± 0.26
Rutherford category	
2	8 (16%)
3	38 (74%)
4	2 (4%)
5	3 (6%)
6	0 (0%)

Abbreviations: ABI, ankle brachial index; GFR, glomerular filtration rate.
[a]Values for patients treated more than once were recorded during the first procedure.
[b]Due to media sclerosis ABI was not detectable in three patients.

as count and percentages, continuous data as mean ± standard deviation, and skewed data as median and ranges. In case of normally distributed values, comparison of within-group data was performed with two-sided paired *t*-test. Otherwise, Mann–Whitney *U* test was applied. A two-sided value of $p < 0.05$ was considered significant.

Results

Baseline Characteristics

Between December 2018 and January 2021, 51 patients were included in the registry. A total of 85 calcified lesions in 61 limbs were treated with IVL (8 patients were treated twice and one patient three times). Patient characteristics are listed in ►**Table 1**. Mean age was 71 ± 8.7 years, 40 patients (78%) were male.

Procedural and Lesion Characteristics

In 42 (69%) interventions, access was gained via femoral crossover approach, in 18 cases (30%) via an antegrade approach, and 1 patient was treated via left brachial access. Thirty-seven (60%) of the IVL interventions were performed via a 6F sheath, and the remaining 25 (40%) via a 7F sheath.

All lesions were highly calcified, corresponding to a PACSS score of 3 to 4 in 68 of 85 lesions (80%) and 13 (15%) were total occlusions. Most lesions ($n = 58$, 68%) were localized in the SFA. The lesion distribution is shown in ►**Fig. 2**. Mean lesion length was 102.5 mm ± 77.2 mm with mean stenosis of 84.5% ± 11%. Predilatation was applied in 34% ($n = 29$) of the lesions. IVL-alone method was used on 49 lesions (58%), followed by subsequent use of DCB in 21 lesions (25%). Embolic protection or atherectomy devices were not used at all. The mean acute lumen gain was 2.6 mm ± 0.9 mm and the final stenosis 42.4% ± 12%.

A complete list of procedural lesion characteristics and adjunctive therapies are listed in ►**Table 2**, a case example is demonstrated in ►**Fig. 3**.

Complications

Considering complications, 11 dissections associated with IVL occurred (12.9%), 6 of them corresponding to National Heart, Lung and Blood Institute grade A and B (7.1%), 4 to grade C (4.7%), and 1 type D dissection (1.1%), classified flow-limiting (≥ D), see ►**Table 2**. Vessel occlusion did not occur.

Acute Results and Intermediate Follow-Up

The baseline ABI, determined for 58 patients, was 0.6 ± 0.26. It was not possible to measure ABI in three patients due to preexisting or new-onset media sclerosis. The ABI increased significantly to 0.8 ± 0.25 ($n = 56$; $p < 0.0001$) on day 1 post-IVL. The post-IVL ABI was comparable to the follow-up value which was measured after (median) 6 months with 0.8 ± 0.27 ($n = 49$; $p < 0.0001$) in comparison to initial ABI. These data are summarized in ►**Fig. 4**.

Baseline treadmill test resulted in a mean walking distance of 160 ± 84 m ($n = 38$) and increased to 194 ± 88 m during follow-up visit, but the difference was not statistically significant ($p =$ not significant).

During the follow-up period, three patients received target vessel revascularization, four patients were lost to follow-up, and two patients died due to unrelated causes before their first follow-up visit.

Discussion

To the best of our knowledge this article describes the largest single-center real-world experience and the first clinical follow-up data of IVL used for treatment of severely calcified lesions in the lower limb. We report safe and feasible clinical routine in patients with severely calcified PAD. IVL resulted in acute angiographic gain of 2.6 mm (42.1%) and led to acute improvement of ABI with sustained success on intermediate follow-up after 6 months.

IVL is a novel method to treat calcified stenotic vessels in peripheral as well as coronary arteries.[21,22] Usually, highly calcified peripheral lesions are excluded from clinical trials because of their difficult preparation, proneness to dissections requiring subsequent interventions, and frequent treatment failures.[6] An advantage of IVL therapy compared with direct atherectomy is the ease of use as with a standard balloon which is inflated with low pressure. Soft tissue from the intimal/medial layer is unaffected by the shockwaves and resulting in a minimal risk of dissection or vessel damage.[35]

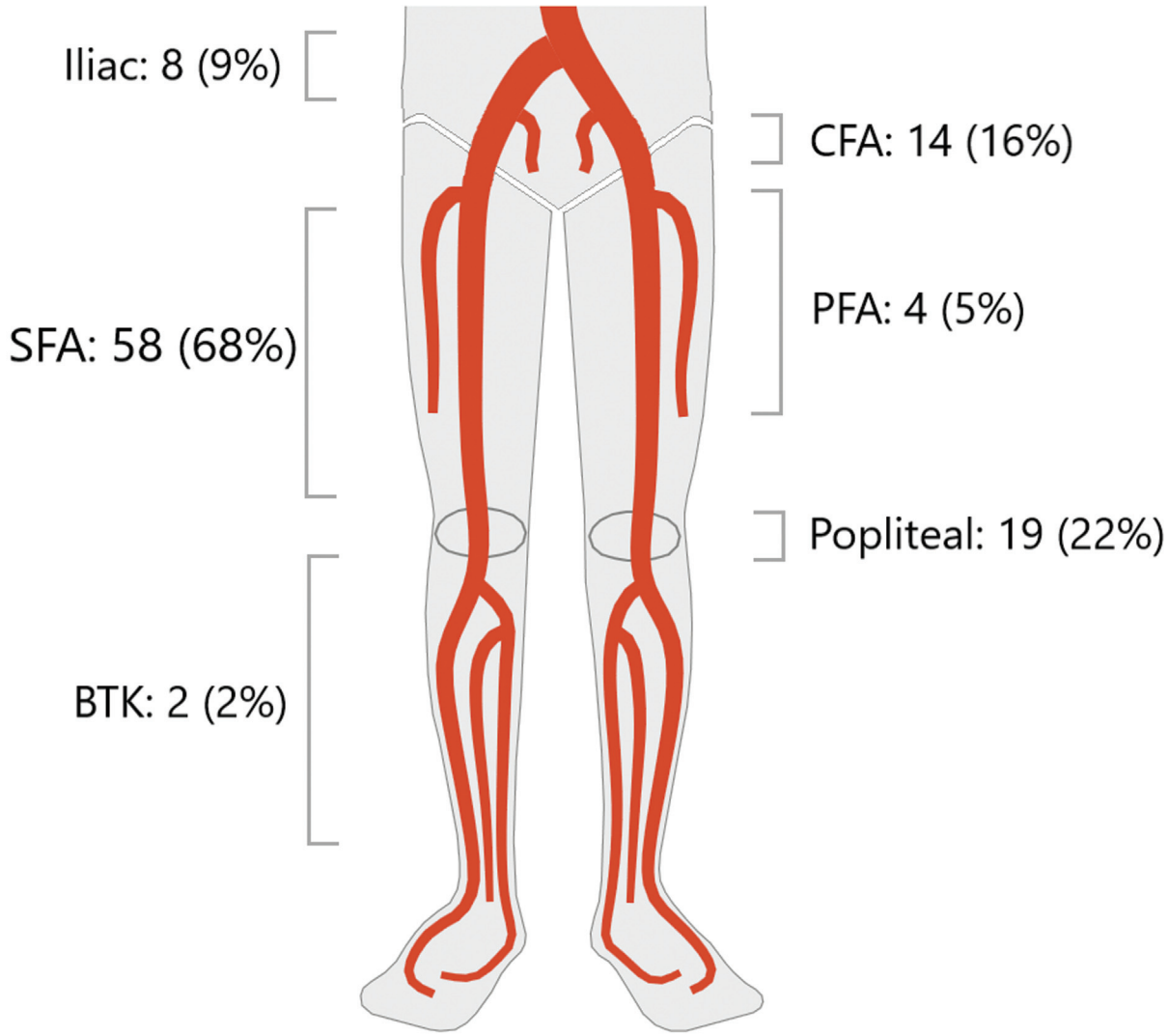

Fig. 2 Peripheral lesion distribution.[44] BTK, below the knee; CFA, common femoral artery; PFA, profound femoral artery; SFA, superficial femoral artery.

Considering the shortcomings of conventional interventional treatment of calcified lesions, together with the controversial results of the meta-analysis by Katsanos et al,[36] our approach was mainly to predilate the lesions and treat them with the IVL balloon as stand-alone approach. This also helps to foreshorten the procedure and to avoid placement of foreign material into the vessel.

Out of numerous proposed systems for grading vessel calcification PACSS score was chosen, as it is attained with fluoroscopy alone. In the DISRUPT-PAD trials the Peripheral Academic Research Consortium (PARC) score was applied. However, both scoring systems are similar in their methodology: they take uni- versus bilateral calcium occurrence into account and combine it with the length of the calcification.[6,37] Although intravascular ultrasound remains the gold standard for peripheral artery calcium studies, it was proven that PARC and PACSS scores provide similar results for calcium classification.[38] The prevalence of severe calcification, described in our trial as PACSS 3 to 4, was 80%, compared with 78% in DISRUPT-III-OS and 82.9% in DISRUPT-III-RT.

Table 2 Lesion and procedural characteristics, complications

Lesion location	
Iliac	8/85 (9%)
CFA	14/85 (16%)
PFA	4/85 (5%)
SFA	58/85 (68%)
Popliteal	19/85 (22%)
BTK	2/85 (2%)
Lesion characteristics	
Lesion length	102.5 ± 77.2 mm
Diameter stenosis, %	84.5% ± 11%
High PACSS (3–4)	68/85 (80%)
MLD	0.88 ± 0.7 mm
RVD	5.7 ± 1.6 mm
CTO	13/85 (14.8%)

(*Continued*)

Table 2 (*Continued*)

In-stent restenosis	5/85 (6%)
Adjunctive therapy	
IVL alone	49/85 (58%)
DCB	21/85 (25%)
Stent	9/85 (11%)
DCB/Stent	5/85 (6%)
Predilatation	29/85 (34%)
Postdilation	16/85 (19%)
Access and sheaths	
Retrograde access	42/61 (69%)
Antegrade access	18/61 (30%)
Brachial access	1/61 (1%)
6 F sheath	37/62 (60%)
7 F sheath	25/62 (40%)
IVL delivery	
Successful IVL delivery	61/61 (100%)
IVL pulses	257 ± 71
IVL Balloon rupture[a]	6/61 (10%)
IVL device error[b]	2/61 (3%)
IVL balloon size	
4.0 mm	1/63
4.5 mm	0/63
5.0 mm	5/63
5.5 mm	12/63
6.0 mm	19/63
6.5 mm	9/63
7.0 mm	17/63
Complications	
Dissections type A-B	6/85 (7%)
Dissections type C	4/85 (4.7%)
Dissections type D (flow-limiting)	1/85 (1.1%)
Vessel occlusion	0/85
Final results	
Stenosis	$42.4\% \pm 12\%$
Acute lumen gain	2.6 ± 0.9 mm
Stenosis reduction	$42.1\% \pm 15\%$

Abbreviations: BTK, below the knee; CFA, common femoral artery; CTO, chronic total occlusion; DCB, drug coated balloon; IVL, intravascular lithotripsy; MLD, minimal lumen diameter; PACSS, peripheral artery calcification scoring system; PFA, profound femoral artery; RVD, reference vessel diameter; SFA, superficial femoral artery.
[a]In 2 cases a second IVL balloon was used after balloon rupture depending on the result, so total number of used balloons is 63.
[b]Error 88 (pulse delivery timeout).

The DISRUPT trials were taken as a point of reference and a comparison of chosen parameters have been summarized in ►**Table 3**. Baseline data of our study shows similar characteristics as in DISRUPT-PAD-III considering age, gender, prevalence of hypertension, and initial ABI (0.6 vs. 0.7). However, the collective presented here was more prone to diabetes (80% vs. 50.5%) and showed slightly less individuals with hyperlipidemia (75% vs. 86.4%). Advanced Rutherford categories (4 and higher) were more common in DISRUPT-III-OS (10% vs. 30.1%) but similar to DISRUPT-III-RT (5.9%).

The lesion characteristics were comparable regarding lesion length (102.5 ± 77.2 mm vs. 103.4 ± 71.9 mm and 100.9 ± 41 mm in both DISRUPT-III trials), severe calcification grade (~80%) as well as initial stenosis ($84.5\% \pm 11\%$ vs. $85\% \pm 12\%$ and $80.8\% \pm 17.9\%$ in DISRUPT-III). The initial RVD was similar (5.6 vs. 5.7 mm $\pm$ 1.6 mm and 5.3 mm $\pm$ 0.8 mm). Lesion localization was also similarly distributed in DISRUPT-III-OS with SFA being the most common region. CTOs were generally more common in DISRUPT-III (32.9% in the observational study and 26.3% in the randomized trial) than in our study (15.3%).

The results of our vessel analysis showed an acute lumen gain of 2.6 mm and a final stenosis of 42.4%. This is markedly higher in comparison to DISRUPT-III-OS (acute lumen gain of 3.4 mm and residual stenosis of $< 30\%$) and more comparable with data of DISRUPT-III-RT (stenosis $< 30\%$ in 66.4% of the cases after IVL but before DCB). Our strategy was primarily to perform a predilatation (34%) and use IVL-only approach (in 58% of all lesions). We applied additional DCB in 25% cases, stents in 11%, and a combination of DCB/stents in 6% of the lesions, which allows us to evaluate IVL with only minor confounder effect. However, the results of DISRUPT-III-OS relied heavily on adjunctive therapy (DCB in 77.7%, stents in 29.9%, atherectomy devices in 19.8%, and specialty balloons in 6.1%). Frequency of subsequent postdilatation (56%) was also markedly higher than in our report (19%). The results of DISRUPT-III-RT after IVL and prior to DCB show more stenosis $> 30\%$, showing some similarity with our results. It seems reasonable that distinctive approach is the main reason for the different angiographic outcome in DISRUPT-III. More frequent diabetes (80% vs. 50.5%) and kidney disease (47% vs. $< 24.3\%$), together with a slightly lower ABI (0.6 vs. 0.7) may indicate more pronounced multimorbidity in our population, supposedly contributing to lower lumen gain. The broader spectrum of lesion localization treated in our study may have also been relevant (DISRUPT-III-RT encompassed only superficial femoral and popliteal arteries). Further difference may also be due to quantification software or the quantification methodology, especially in long stenoses, where, for example, calculation of vessel reference diameter may be less valid.

IVL treatment led to a significant clinical improvement of ABI from mean baseline of 0.6 to 0.8 on day 1 post-IVL. The ABI remained stable at 6 months (►**Fig. 4**). In DISRUPT-II, the only trial with clinical data, the ABI preintervention was 0.7 and rose to 1.0 on discharge and remained stable after 6 months and 1 year. However, due to the nature of the safety trial, the patient cohort in DISRUPT-II were limited to lower Rutherford category (2–3), carried shorter mean

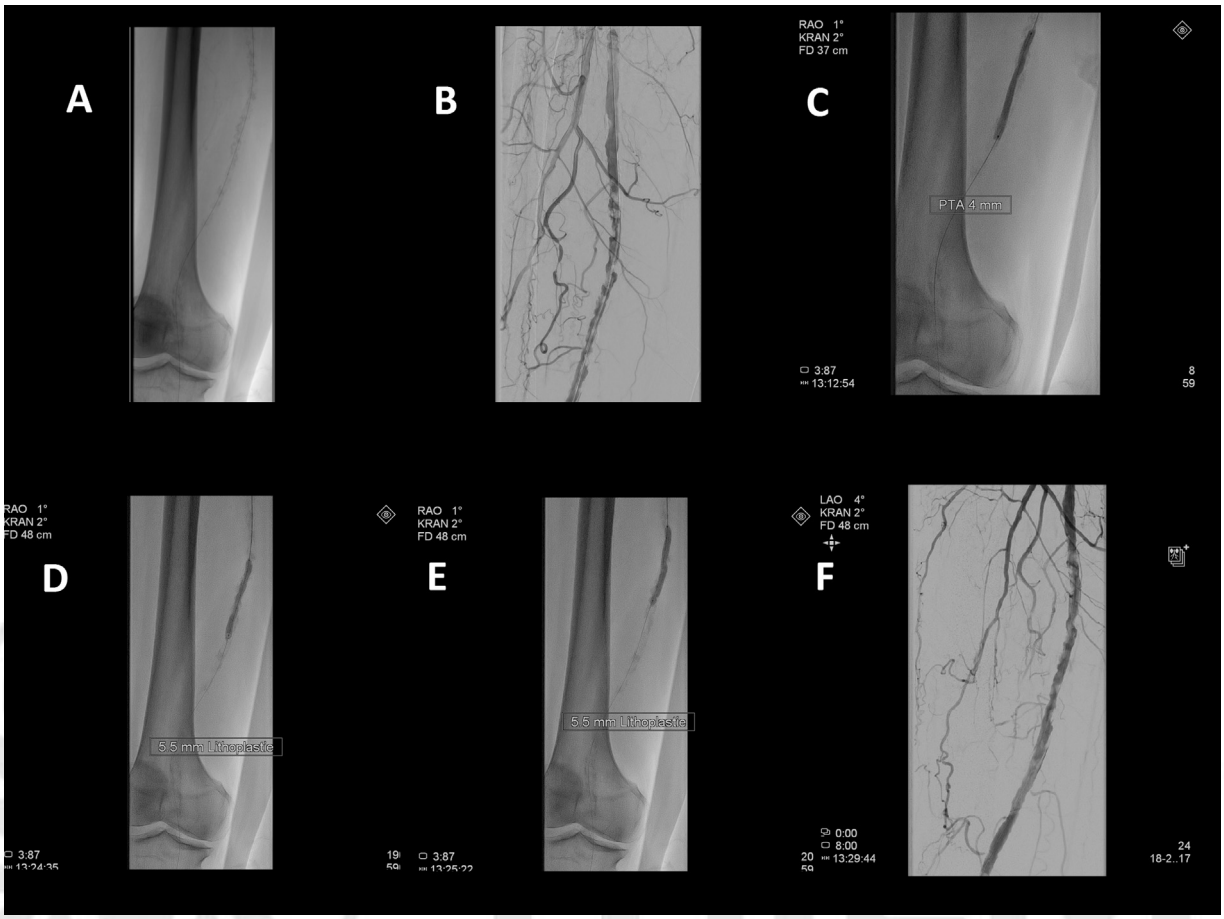

Fig. 3 Steps of an exemplary lithoplasty procedure. (**A**) Native fluoroscopy showing severe calcification of the superficial femoral artery (SFA). (**B**) Angiography before the intervention. (**C**) Predilation with an undersized balloon. (**D**) Intravascular lithotripsy (IVL) application. (**E**) IVL application, demonstrating recommended overlap. (**F**) Final result.

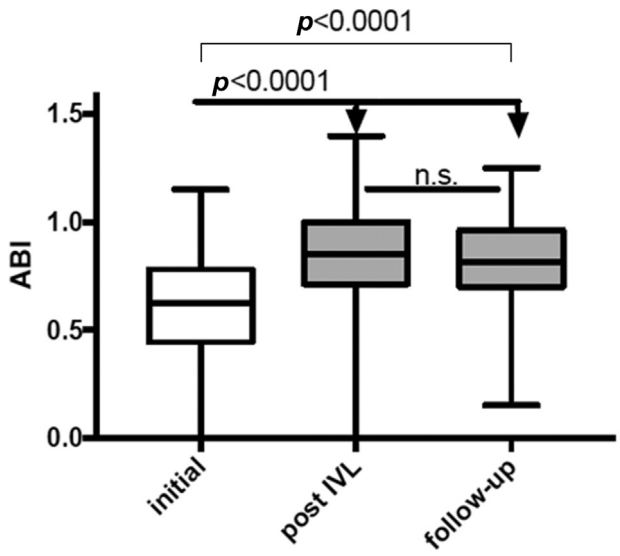

Fig. 4 Ankle brachial index (ABI) course. Initial: ABI before intravascular lithotripsy (IVL) procedure. Post-IVL: ABI one day after IVL procedure. Follow-up: ABI after 6 months.

stenoses (76.9 mm vs. our 102.5 mm), and had less cases of diabetes (80% vs. 56.7%). This is the first study to describe the sustainable effect of IVL PTA over a longer period in a real-world setting even in patients where IVL was used as stand-alone therapy. Considering the positive and stable clinical outcome of our primarily IVL-only approach, a fundamental question arises, whether it is imperative to pursue as low final stenosis as possible. Therefore, the outcome of this study and DISRUPT-III remains to be seen in further follow-ups.

We report low complication rate of only one flow-limiting dissection (►**Table 2**). Our data demonstrate that IVL is suitable for common femoral artery (CFA) lesions, confirming the trend to perform endovascular interventions in this localization.[39,40] One patient was treated prior to a transcatheter aortic valve replacement procedure, a strategy reported in many other cases.[28,41–43] As rupture of the lithoplasty balloon occurred in 6/61 (10%) of procedures, especially at the beginning of this study, predilatation was performed more frequently. In 3% of IVL procedures a device error occurred, leading to malfunction of the balloon either due to an electronic defect of the balloon itself or the cable of

Table 3 Comparison of selected data with former IVL trials

	DISRUPT-PAD II Safety trial $N=60$	DISRUPT-PAD-III		JenExperience $N=51$
		Initial OS $N=200$	RT, IVL arm $N=153$	
Baseline characteristics				
Diabetes	56.7%	50.5%	42.1%	80%
Kidney disease	28.3%	17.8%	24.3%	47%
Rutherford 4+	- (only 2–3)	30.1%	5.9%	10%
CTO	–	32.9%	26.3%	15.3%
Baseline ABI	0.7	0.7 ± 0.3	0.74 ± 0.20	0.6 ± 0.26
Severe calcification	85%	77.9%	82.9%	80%
Lesion characteristics				
Lesion length	76.9 ± 34.8 mm	103.4 ± 71.9 mm	100.9 ± 41 mm	102.5 ± 77.2 mm
Initial stenosis	78.2 ± 13.5 mm	85% ± 12%	80.8% ± 17.9%	84.5% ± 11%
Initial reference vessel diameter	5.4 ± 0.8 mm	5.7 mm ± 1.6 mm	5.3 ± 0.8 mm	5.7 ± 1.6 mm
Iliac	0%	14.8%	0%	9%
CFA	0%	12.5%	0%	16%
PFA	0%	0%	0%	5%
Popliteal	26.7%	14.4%	18.3%	22%
SFA	73.3%	56%	81.7%	68%
BTK	0%	2.3%	0%	2%
Adjunctive therapy				
Predilatation	13.3%	31%	17.6%	34%
Postdilatation	3.3%	50.8%	5.2%	19%
DCB	0%	77.7%	95.4%	25%
Stents	1.7%	29.9%	4.6%	11%
Atherectomy	0%	19.8%	0%	0%
Embolization filters	3.3%	16.2%	1.3%	0%
Specialty balloons	0%	6.1%	0%	0%
Complication	0%	0%	0%	0%
Results				
Acute lumen gain	3.0 ± 0.8 mm	3.4 ± 1.2 mm	Not described	2.6
Final stenosis	24.2 ± 5.7%	23.6%	27.3% (post-IVL) 21.5% (final)	42.4% ± 12%
ABI 6 months post-IVL	1.0	n/a	n/a	0.8 ± 0.27

Abbreviations: ABI, ankle-brachial-index; BTK, below the knee; CFA-common femoral artery; CTO, chronic total occlusion; DCB, drug coated balloon; IVL, intravascular lithotripsy; n/a, not available; OS, observational study; PFA, profound femoral artery; RT, randomized trial; SFA, superficial femoral artery.

the IVL console. These issues were not reported in the DISRUPT publications.

Advantages of IVL

The IVL system does not require a filter system for distal embolization, and it does not damage the surrounding soft tissue. It carries a low risk of dissection and no risk of vessel perforation. IVL seems to be a feasible stand-alone treatment concept also after consideration of longer time follow-up. IVL has the potential to overcome disadvantages of stent implantation (fracture, stent thrombosis, in-stent restenosis).

Disadvantages of IVL

We look forward to improvements considering the larger balloon diameter which would be feasible in therapy of the iliac vessels (currently only up to 7.0 mm diameter available). The high cost of the device remains to be considered and precautions must be made to minimize balloon rupture. Additionally, the system's compatibility with exclusively

0.014" guidewires leads to lower pushability of the balloon, especially in high-grade stenoses with severe calcifications.

Limitations of this Study

Only two cases with a BTK IVL procedure were included in this study. The follow-up was limited to 6 months, but long-term data are currently lacking. Intravascular ultrasound could provide more insight on vessel calcification depth and effects of IVL in a population prone to multimorbidity.

Conclusion

The safety and efficacy of IVL procedures in the challenging setting of severely calcified PAD can be confirmed in this all-comers real-world registry. An improvement of ABI after IVL treatment, which remained stable after a follow-up period of 6 months, can be reported.

Outlook

Further prospective studies of severely calcified PAD lesions are required to compare different techniques of vessel preparation (atherectomy, IVL, scoring balloons) with or without drug-eluting technologies or other adjunctive therapies. We look forward to seeing the clinical and functional results of the DISRUPT-PAD-III trial including follow-up data after 24 months.

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Conflict of Interest
None declared.

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