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Focal Stenting of Complex Femoropopliteal Lesions with the Multi-LOC Multiple Stent Delivery System: 12-Month Results of the Multicenter LOCOMOTIVE Study

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Abstract

Introduction The purpose of this observational study is to report the 12-month clinical outcomes with the novel Multiple Stent Delivery System (MSDS) to treat complex femoropopliteal lesions. Previously, we reported the 6-month clinical outcomes of the all-comers LOCOMOTIVE study, which demonstrated the safety and efficacy of the MSDS with a favorable target lesion revascularization (TLR) rate of 5.3% and a 90.7% patency rate at 6 months in claudicants and critical limb ischemia patients. The 12-month outcomes of LOCOMOTIVE registry are presented in this report. ClinicalTrials.gov Identifier: NCT02531230.

Methods The LOCOMOTIVE study (Multi-LOC for flOw liMiting Outcomes after POBA and/or DCB Treatment in the infrainguinal position with the objecIVE to implant multiple stent segments) investigates the efficacy and safety of the MSDS approach in an all-comers population. Clinical follow-ups at 6 and 12 months are scheduled to assess TLR, ABI, and vessel patency based on sonographic imaging.

Results At 12 months, the primary unassisted patency was 85.7% and all-cause TLR rate was 9.3% in the overall cohort. Between baseline and 12 months, the target leg ABI increased from 0.62 ± 0.24 to 0.91 ± 0.38 ($p < 0.001$) and the mean Rutherford class improved from 3.5 to 1.9 ($p < 0.001$).

Conclusions Over a 12-month post-procedural period, MSDS for focal provisional stenting of complex femoropopliteal lesions demonstrated a promising primary patency and freedom from TLR after 12 months. In addition, significant improvements were observed in symptom classification and hemodynamics.

Keywords Femoropopliteal lesions · Multiple stent segments · Target lesion revascularization · Patency

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Introduction

Percutaneous interventions have evolved to a first-line treatment modality for femoropopliteal atherosclerotic lesions [1–3]. Endovascular approach is changing toward a differentiated physiological treatment taking into account

lesion morphology, length, and location [4, 5]. While antiproliferative drug delivery has an important role in femoropopliteal interventions, treatment algorithms still rely on mechanical treatment modalities. These do include stent implantations as a bailout option in case of suboptimal angiographic results after plain old balloon angioplasty (POBA) or drug-coated balloon (DCB) angioplasty.

The MSDS approach enables focal stent implantations of multiple femoropopliteal segments, optimizing procedural device handling with up to six short stents per delivery device, each 13 mm in length, can be implanted. In comparison, the Tack Endovascular System™ has an individual stent length of 6 mm and is therefore substantially shorter than the 13 mm long stents of the MSDS used in this study. The LOCOMOTIVE all-comers registry (NCT02531230) documents procedural data, as well as preliminary safety and efficacy data. This all-comers observational study comprised a total of 75 patients [73.3% claudicants, 26.7% critical limb ischemia (CLI)], aged 72.9 ± 9.2 years with femoropopliteal lesions having a length of 14.5 ± 9.0 cm and 51.1% TASC C/D lesions.

The 6-month results of the primary end point (TLR) have been previously published [6], which revealed a 6-month TLR rate of 5.3% (4/75). The 12-month clinical outcomes of the LOCOMOTIVE registry are presented in this manuscript.

Methods and Results

Study Design and Patients

LOCOMOTIVE is an all-comers, single armed, observational study (ClinicalTrials.gov Identifier: NCT02531230) conducted in high-volume German vascular centers. The primary end point was the all-cause target lesion revascularization (TLR) rate at 6 months whereas the ankle-brachial indices (ABI), walking distance (WD), and the patency rates determined with duplex ultrasound at 6 and 12 months were used as secondary end points. Additional details of the study methodology are provided in a previous publication [6]. Clinical follow-up at 6 and 12 months was scheduled for all patients including ABI measurements and the determination of the peripheral artery disease stages (Rutherford clinical classes). Patency was defined as diameter stenosis $< 50\%$ according to recommended reporting standards [7], based on sonographic data and complemented by angiograms in case a Duplex/Doppler was not available. All adverse events including minor and major amputations and/or were recorded with a dedicated data capture system.

Study Devices

The Multiple Stent Delivery System (MSDS) used in this assessment (VascuFlex® Multi-LOC, B.Braun Melsungen AG, Fig. 1) was previously reported to have favorable outcomes at 6 months [6]. Briefly, the MSDS has six individual closed cell design stents each 13 mm in length which are all mounted on a single catheter. By pulling back the outer catheter sheath, these stents can be subsequently released with a turn-wheel mechanism. The devices are available in shaft lengths of 80 cm and 130 cm while being 6F compatible.

Comedication

Due to the all-comers character of this study, clinical routines were followed in each vascular center. Heparin 25–100 U/kg body weight, i.a. upon insertion of the sheath was given. In procedures lasting > 1 h, either 75 U/kg body weight or 5000 U i.a. of heparin was recommended. Aspirin $\geq$ 100 mg/d orally was indicated life long. Clopidogrel was given at a dose of 75 mg/d for 1 month unless there was an extended need for longer anti-platelet therapy. No change of concomitant therapy unless medically necessary was recommended.

Ethics

Following the lead ethics approval at Medizinische Ethik-Kommission II of the Ruprecht-Karls-Universität Heidelberg, additional ethics votes were obtained at Chambers of Physicians in Berlin, Hamburg, Bavaria, Baden-Württemberg, Saxony-Anhalt, and Saxony. All patients were informed and consented prior to inclusion in this study.

Statistical Analysis

The Pearson Chi^2 test was used to analyze dichotomous variables. Moreover, the Mann–Whitney *U* test was used to analyze continuous variables in case the Shapiro–Wilk test revealed a strong deviation from normal distribution. Otherwise, the unpaired *t* test was utilized. However, the paired *t* test was applied for Rutherford classes per patient at different time points. For ABI measurements, the repeated measurement ANOVA was utilized. All statistical analyses were done with SPSS version 24 (IBM, Munich, Germany).

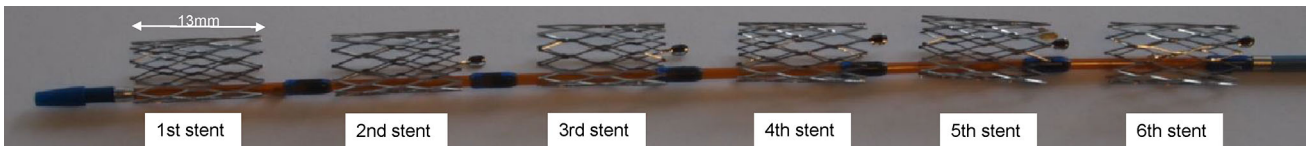

Fig. 1 MSDS with all six stents after sheath pullback

Results

Patient, Lesion, and Procedural Characteristics

A total of 75 patients (72.9 ± 9.2 years of age) with symptomatic peripheral artery disease were enrolled between July 2015 and July 2016, with about one-fourth of the recruited patients suffering from CLI. There were no device-related complications at baseline and all stent segments could be implanted in the target lesions [6]. The primary unassisted patency at 6 months as reported in the original manuscript was 90.7% (68/75) and all-cause TLR rate was 5.3% (4/75) in the overall cohort [6]. As previously published [6] only 53 ± 18% of the total lesion lengths were stented with the 13 mm MSDS segments. Therefore, 47 ± 18% of the lesion length was saved from stenting.

Clinical Results at 12 Months

Clinical outcomes at 12 months are shown in Table 1. The primary unassisted patency rates and the all-cause TLR rates at 6 and 12 months are shown in Fig. 2. There were four TLRs (5.3%, Re-PTA, lysis) at 6 months and 7 (9.3%) at 12 months, respectively. The difference between 6- and 12-month TLR was 4.0%.

Between baseline and 12 months, the target leg ABI increased from 0.62 ± 0.24 to 0.91 ± 0.38 ($p < 0.001$, Fig. 3) and the mean Rutherford class decreased from 3.5 to 1.9 ($p < 0.001$, Fig. 4). Between 6 and 12 months, neither target leg ABI, nor Rutherford-Becker class changed significantly (ABI: $p_{\text{post vs. 12 months}} = 0.343$, Rutherford-Becker: $p_{\text{6 months vs. 12 months}} = 0.397$). Between 6 and 12 months, four non-CLI patients died from non-cardiovascular causes.

Discussion

Our study did not include a control group. Therefore, we cannot claim superiority of the multiple stent delivery system to other devices based on these results. This all-comers study documents preliminary safety and efficacy data of the MSDS approach, to treat steno-occlusive femoropopliteal artery disease in Rutherford class 2–5 patients.

To minimize damage particularly in motion segments, the "leave nothing or little behind" strategy combined with a minimized chronic outward force as compared to longer stents seems reasonable. Limiting stent implantations to segments, where scaffolding properties are needed after balloon dilatation, are believed to foreign body interaction with the vessel wall and potentially reducing neointimal proliferation as seen in our preclinical study [8]. Both clinical experience and published trials support the concept that the risk of restenosis, following intervention, might positively correlate with the length of the diseased and/or stented femoropopliteal segment [9]. Spot stenting has demonstrated favorable clinical results in conceptual research with a significantly higher primary patency rate compared with implantations of long stents, following (subintimal) approach for long chronic total occlusions in the femoropopliteal artery [10].

In the past, DCB seemed to shift femoropopliteal treatment paradigms away from stenting to non-stent-based treatments. However, long-term results suggested that DCBs were safe and effective in "delaying rather than preventing restenosis in long, complex lesions" [11] and most randomized DCB-trials included only relatively short target lesions from a clinical reality point of view. In the PACIFIER [12] (DCB-arm: 7.0 ± 5.3 cm), LEVANT I [13] (DCB-arm: 8.1 ± 3.7 cm) THUNDER [14] (DCB-arm: 7.4 ± 6.7 cm), or the BIOLUX P-I trial [15] (DCB-arm: 5.1 ± 4.7) the lesion lengths were approximately half as long as in our study. The CONSEQUENT trial (DCB-Arm 13.7 ± 12.2 cm) featured the longest lesions of any other previously published DCB-trial in a Caucasian patient population [16], showing a TLR rate of 17.8% in the DCB-arm at 12 months. Nevertheless, in all these studies, stenting was indispensable with bailout stent rates in the DCB groups from 3 to 20%.

One discussion point from our viewpoint is the so-called edge effect which would theoretically occur at every stent edge. To our knowledge, there is only one report of edge effects of the Viabahn stent graft [17] which was explained primarily with poor runoff. However, the higher stenosis rates at stent edge are primarily observed in coronary stenting. The latter, we sense, is a side effect of balloon expandable stent implantations which is described as balloon "dog-boning," i.e., a higher balloon diameter at either

Table 1 Clinical outcomes at baseline and at 12 months

	All patients	Critical limb ischemia	No critical limb ischemia	*P* value
Patients	75	20	55	–
Pre-procedure				
Walking distance (m)	98.3 ± 82.1	17.5 ± 17.7	101.9 ± 82.0	0.010
Target leg ABI	0.62 ± 0.24	0.40 ± 0.18	0.69 ± 0.21	< 0.001
Post-procedure (in hospital)				
Target leg ABI	0.90 ± 0.25	0.80 ± 0.28	0.93 ± 0.20	0.042
12 months				
Number of follow-ups sonographic, clinical and telephone	75 (100.0%)	20 (100.0%)	55 (100.0%)	–
Duration to follow-up or event, months	11.8 ± 3.0	10.8 ± 4.2	12.1 ± 2.3	0.186
Primary unassisted patency[a], diameter stenosis < 50%	54 (85.7%)	14 (93.3%)	40 (83.3%)	0.334
	n = 63	*n* = 15	*n* = 48	
All Target lesion revascularizations (Re-PTA, lysis)	7 (9.3%)	1 (5.0%)	6 (10.9%)	0.437
	n = 75	*n* = 20	*n* = 55	
Target vessel revascularization (Re-PTA, lysis)	9 (12.0%)	2 (10.0%)	7 (12.7%)	0.748
	n = 75	*n* = 20	*n* = 55	
Non-target vessel revascularization				
Re-PTA	6 (8.8%)	2 (10.0%)	4 (5.5%)	0.069
Surgical bypass	4 (5.3%)	3 (15.0%)	1 (1.8%)	
Walking distance[1], pain-free (m)	116 ± 51	92 ± 43	120 ± 52	0.680
	n = 26	*n* = 3	*n* = 23	
Target leg ABI	0.91 ± 0.38	0.91 ± 0.40	0.91 ± 0.38	0.973
	n = 53	*n* = 13	*n* = 40	
Rutherford shift pre versus 12 months	2.2 ± 1.3	2.8 ± 1.7	2.1 ± 1.0	0.038
	n = 60	*n* = 15	*n* = 45	
Major amputations, target leg	2 (2.7%)	2 (10.0%)	0 (0.0%)	0.017
	n = 75	*n* = 20	*n* = 55	
Major amputations, contralateral leg	1 (1.3%)	1 (5.0%)	0 (0.0%)	0.095
	n = 75	*n* = 20	*n* = 55	
Death all causes	9 (12.0%)	3 (15.0%)	6 (10.9%)	0.630
	n = 75	*n* = 20	*n* = 55	
Death				
Cardiac	1 (1.3%)	0 (0.0%)	1 (1.8%)	0.398
Vascular	3 (4.0%)	2 (10.0%)	1 (1.8%)	
Non-cardiovascular	5 (6.7%)	1 (5.0%)	4 (7.3%)	

[a]Based on angiographic or sonographic data only

All categorical variables were compared with the Pearson's Chi^2 test; continuous variables were analyzed with the unpaired student *t* test

end of the balloon. This in turn leads to overexpansion and higher intimal injury at these balloon ends which are believed to be the main culprit for stent end stenosis.

In case of suboptimal results (flow-limiting dissection or recoil) post-dilatation, "bailout" stenting of the full lesion length is common practice. In this context, the major advantage of the MSDS compared to other single stent delivery systems is the possibility to release up to six short stents without changing the delivery system. We believe that the combination of balloon dilatation (POBA or DCB) and/or atherectomy with (bailout) spot stenting might be a promising concept in calcified lesions and dissections. With a lesion length of 14.5 ± 9.0 cm in the overall cohort and 19.0 ± 9.5 cm in the CLI patient group, more than half of all treated lesions (51.1%) were TASC C/D lesion types. In comparison with lesion lengths of benchmark studies of self-expanding Nitinol stents in the femoropopliteal vasculature such as the RESILIENT trial ([18], mean lesion length of 7.1 cm for the stent group) with comparable one-year patency and TLR rates, the mean lesion length of our

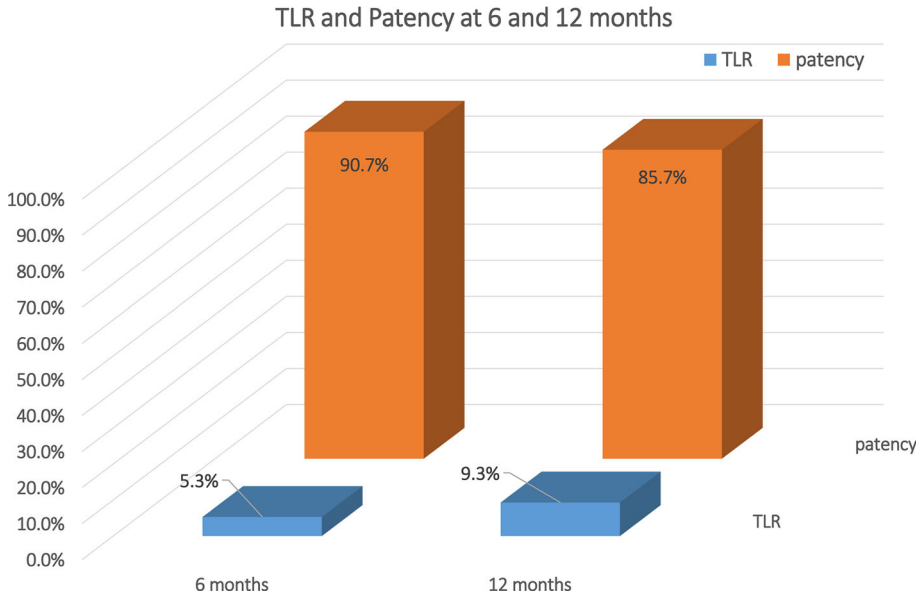

Fig. 2 All target lesion revascularizations (TLR) and primary unassisted patency at 6 and 12 months

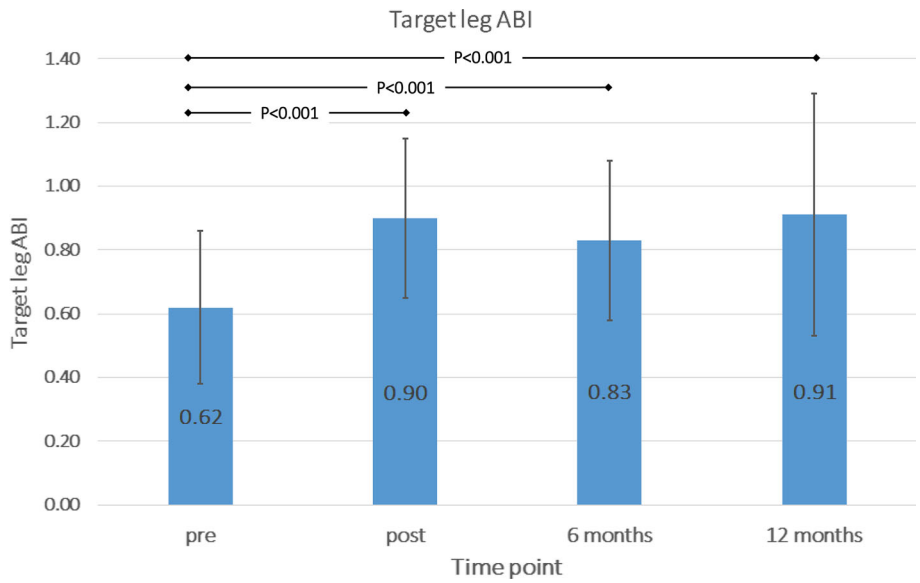

Fig. 3 Target leg ankle-brachial index (ABI) post-interventional and at the 6- and 12-month follow-up versus pre-interventional (pairwise comparison based on repeated measurement ANOVA)

registry data was about twice as long. Notably, the Zilver PTX Post-Market Surveillance Study [19] enrolling more than a thousand also complex lesions with an average length of 14.7 cm revealed a 12-month primary patency rate of 86.4% and the freedom from TLR was 91.0%. These results were similar to our findings despite the fact that a direct and unmatched comparison between studies is statistically not admissible.

The results of the REAL-PTX randomized clinical trial comparing Zilver PTX versus DCB plus bailout (non-drug eluting) stenting in femoropopliteal lesions revealed no difference at 12 months for the total group. The most striking result of this trial is that in the subgroup of "DCB only patients" with long lesions (more than 20 cm) patency was significantly inferior to DES, with an impressive drop of patency 400 days after treatment [20]. This underlines that stenting in long lesions is essential for long-term patency, even after DCB treatment.

With more than 90% of all patients showing severe target lesion calcification and a target lesion total occlusions rate of 15.3%, our baseline data is quite representable for our routinely treated patients. While the implantation of small Nitinol rings to fix dissecting membranes after PTA has led to promising results in short and less calcified lesions [21], the Tack Endovascular System™ (Intact Vascular, USA) may not be suitable for severely calcified lesions or pronounced vessel recoil due to their lower scaffolding capacity, i.e., a lower radial force as compared to the MSDS used in this study.

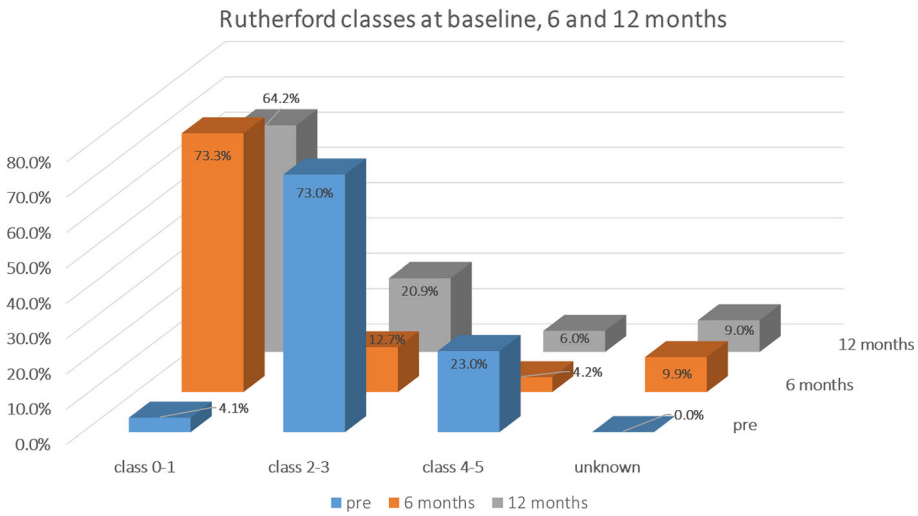

Fig. 4 Rutherford classes pre-intervention and at the 6- and 12-month follow-ups

Promising patency rates were observed with so-called vascular mimetic stent designs, such as an interwoven nitinol stent. With its six interwoven nitinol wires in a closed-loop design, the Supera peripheral stent (Abbott Vascular, USA) combines flexibility with high compression resistance for calcified femoropopliteal lesions. While patency in the SUPERB Trial ([22], lesion length 7.8 ± 4.3 cm) was high, the SAKE-COMPEL sub-study [23] with a lesion length (138.9 ± 95.8 cm) similar to our study, showed an unassisted patency rate of 69.5%. Moreover, a nominal stent conformation was observed which revealed an extensive effect on deployment characteristics with a patency rate ranging from 85.2%, for minimal to moderate stent compression, to 64.7% for moderate to severe stent elongation. In contrast, spot stenting saves space for further surgical treatment by conventional bypass surgery with stent-free landing zones for distal or proximal anastomoses in case of incomplete lesion reocclusion.

Consequently, we assume that with increasing complexity of the lesion, the need for at least a segmental mechanical stabilization such as a bailout stent is essential for long-term patency. Focal stenting seems to be superior to full metal jacket stenting [10]. However, data in the femoropopliteal vasculature is rare and randomized controlled trials are missing. Our strategy of combining balloon dilatation with focal stenting shows (1) technical feasibility and safety of multiple focal stenting with MSDS, (2) promising primary patency rates and freedom from TLR in all-comer lesions even after POBA, and (3) favorable clinical results (Rutherford class, ABI). Future studies comparing DCB and focal stenting on one side and DCB combined with long bare metal stents will be crucial. In addition, future studies with modern paclitaxel-coated peripheral stents such as the Eluvia® stent (Boston Scientific Corp, USA) in the control arm and drug-coated MSDS may also be a research avenue to be explored.

Study Limitations

The main limitation of this study is the absence of a control group. A larger randomized trial or a properly propensity scored matched patient population are needed to compare the focal stenting strategy to conventional interventions with long stents. Furthermore, there was no adjudication by an independent core laboratory; however, multiple enrolling centers were in charge of collecting and reporting the data. Moreover, predilatation with DCB or POBA was both permissible prior to stenting. This may have introduced additional bias, i.e., center effects since preferences for predilatations, may have correlated with the procedural routines in vascular centers. Furthermore, lesions in one patient were not predilated and constituted therefore a protocol violation.

Conclusions

Over a 12-month surveillance period, the use of the MSDS for focal provisional stenting of complex femoropopliteal lesions showed promising results. The overall primary patency was 85.7%, freedom from TLR was 90.7% at 12 months in morphologically challenging lesions. Almost half of the lesion length could be saved [6] from stenting as compared to the full metal jacket strategy.

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investigator (KA). The first draft of the paper was prepared by MS and MW.

Compliance with Ethical Standards

Conflict of interest KA and RL have received lecturer honoraria and research grants from B.Braun to conduct this study. MW is a full-time employee in the Medical Scientific Affairs department of B.Braun Melsungen AG, Vascular Systems, Berlin/Germany. TZ received honoraria from Abbott Vascular, Bard Peripheral Vascular, Biotronik, Boston Scientific Corp., Cook Medical, Gore and Associates, Medtronic, Philips-Spectranetics, TriReme, Veryan, Shockwave, Biotronik, QT Medical and consulted for Boston Scientific Corp., Cook Medical, Gore and Associates, Medtronic, Spectranetics, and B.Braun.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study. This study has obtained IRB approval from the Ethics Committee University Heidelberg/Mannheim and an informed consent was reviewed and authorized by this lead ethics committee and all other ethics committees that were responsible for the participating centers.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study. There are no individual data of adult patients in any form published in this report.

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