Lucerne milestone approach for benchmarking and education: Towards ultra-low dose endovascular aortic repair

Maani Hakimi, MD,^a Alina Reeg, MD,^a Juan Antonio Celi de la Torre, MD,^a Georg Jung, MD,^a Tomàs Reyes del Castillo, MD,^b Justus Roos, MD,^b and Thiago Lima, MD,^b Lucerne, Switzerland

ABSTRACT

Objective: The aim of this single-center case series is to demonstrate that an ultra-low dose (ULD) can be routinely achieved in the hybrid operating room in standard endovascular aortic repair (EVAR) for infrarenal abdominal aortic aneurysm by adjusting the manufacturer's predefined imaging parameters, hardware configurations and user protocols (including benchmarking).

Methods: The hybrid operating room manufacturer predefined EVAR software setup of the dose exposure control software (OPTIQ, Siemens Healthineers, Forchheim, Germany) at our university medical center was screened for possible improvements regarding radiation dose application. Tests on a water-equivalent as well as polymethyl methacrylate phantom model to assess the impact of technical settings were performed, including comparison of settings for exposure control software, different magnification, collimation configurations and detector distance. All results were transferred into modified setups for the exposure control software and a new ULD procedure protocol for EVAR. Additionally, to standardize the clinical pathway, the Lucerne EVAR Milestone Approach (LEMA) was introduced including preoperative, perioperative, and postoperative milestones for technical procedure content and dose benchmarking during EVAR. A validation of the new settings including revised software setup, procedure protocol, and applicability of LEMA on a consecutive EVAR case series was conducted. Ten consecutive patients undergoing EVAR for low and medium complexity infrarenal abdominal aortic aneurysm were included. The primary outcome parameter was intraoperative dose area product (DAP, measured in Gy·cm²). Secondary outcomes were median fluoroscopy time (in minutes:seconds), cumulative air kerma (in mGy), clinical success, and occurrence of endoleaks.

Results: New ULD settings compared with previous manufacturers standard settings of dose exposure control software reduced DAP for both fluoroscopy (0.0382 Gy·cm²/min vs 0.3 Gy·cm²/min) and angiography (2.36 Gy·cm²/min vs 2.48 Gy·cm²/min). Digital magnification and collimation decreased DAP. Application of the new ULD standard EVAR protocol resulted in a median DAP of 5.6 Gy·cm² (range, 3.54-12.1 Gy·cm²). Median fluoroscopy time was 16 minutes and 32 seconds. Type I endoleaks occurred in no patients (0%), type II in five patients (50%), and type III in no patients (0%). No patient had to undergo reintervention owing to endoleak or absence of diameter shrinkage during the first postoperative year.

Conclusions: Revision of the manufacturer-predefined EVAR setup by testing and ensuring optimal imaging parameters and hardware configurations in combination with LEMA enabled performance of ULD standard EVAR procedures routinely without compromising imaging quality. (J Vasc Surg Cases Innov Tech 2025;11:101705.)

Keywords: Endovascular aneurysm repair; Aortic aneurysm abdominal; Radiation dosage; Dose area product

The technical environment for imaging in hybrid operating rooms (HOR) is an innovative and crucial aspect in reducing radiation dose. Endovascular techniques for treating aortic pathologies have been implemented for

approximately 30 years.^{1,2} Since the early 2000s, fenestrated and branched aortic grafts have been increasingly developed followed by techniques to even treat the aortic arch with fenestrated stent grafts during the last decade.^{3,-5} In summary, complex endovascular methods have been established in specialized clinics, with focus shifting from feasibility to workflow optimization and procedure enhancement.^{6,7}

Consequently, radiation exposure durations and amounts of radiation per procedure are increasing, both individually and cumulatively.⁸ This trend results in escalating radiation exposure not only for patients, but also for operating room personnel.^{9,10} Scientific literature reports a wide spectrum of dose area products (DAPs) for standard endovascular aortic repair (EVAR) in HORs from 12 Gy cm² up to 181 Gy·cm^{2,11,12} The average DAPs reported in studies using mobile C-arms or fixed

From the Department of Vascular Surgery, and Department of Radiology and Nuclear Medicine, University Teaching and Research Hospital Lucerne.

Additional material for this article may be found online at www.jvscit.org.

Correspondence: Alina Reeg, MD, Department of Vascular Surgery, University

Correspondence: Alina Reeg, MD, Department of Vascular Surgery, University Teaching and Research Hospital Lucerne, Spitalstrasse, Luzern 6000, Switzerland (e-mail: alina.reeg@luks.ch).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2468-4287

© 2024 The Authors. Published by Elsevier Inc. on behalf of Society for Vascular Surgery. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

https://doi.org/10.1016/j.jvscit.2024.101705

imaging systems reach even higher.¹³ Thus, dose reduction during EVAR plays an elemental role in workflow optimization.

The increasing effort to reduce dose has been accompanied by the introduction and development of HORs. 14,15 This process also includes cultivation of a dose-saving mindset to decrease exposure for patients and staff alike.^{16,17} With the newest generation of HORs, dose reduction and associated image quality improved significantly influenced by the software behind this technology. Also, image fusion software techniques with navigation tools enable high end surgery with even lower radiation doses.¹⁸ Adjunctive guidance technologies, such as fiberoptic real shape (FORS) or use of intravascular ultrasound (IVUS) examination, are also increasingly implemented. To closely adhere to as low as reasonably achievable (ALARA), detailed understanding of the angiographic imaging system is key. However, evidence for the most efficient technical approaches to dose reduction in a modern HOR remains limited, despite the available literature on perioperative radiation reduction, suggesting limited technical knowledge of respective tools among vascular surgeons. 19,20

The objective of this study was to demonstrate that knowledge of technical environments enables optimization of imaging parameters and hardware configuration and thus allows standard EVAR to be performed routinely as ultra-low dose (ULD) procedure, defined as a DAP of $<10~{\rm Gy\cdot cm^2}$.

METHODS

Study overview and software configuration. Before the conduct of this study, the HOR system (ARTIS pheno robotic C-arm, Siemens Healthineers, Forchheim, Germany) was using software version VE10 and exposure control software was set with factory setup. After the installation of a premarket contrast-to-noise ratio (CNR) exposure control software test version, pretests were performed during EVAR with the adaption of CNR settings towards surgeons ALARA preferences resulting in low-dose setup and ULD setup (for details see the Appendix).

With these setups as a starting point, this study was conducted in two steps. First, preliminary tests on phantoms were carried out to validate the adapted CNR exposure control software settings. Simultaneously, the previous surgical standard operating protocol (prSOP) for standard EVAR was fundamentally revised. Standard EVAR was defined as without fenestrations, branches, surgical modifications, or snorkel techniques. To coordinate the new ULD-SOP with technical settings of the HOR and to monitor dose, Lucerne EVAR Milestone Approach (LEMA) was introduced. LEMA divides the whole EVAR procedure of indicating, sizing, planning, performing and documenting in different workflow

steps (milestones). LEMA was also implemented to standardize reporting of the workflow and dose levels (per milestone). For each milestone, quality standards, surgical manual steps, imaging parameters and reporting are defined.

Second, ULD software setup including the adapted CNR premarket version with a new ULD organ dose program as a part of the exposure control software, surgical ULD-SOP and LEMA were tested on a case series. As an outcome of the study, the VE2O software has been released to the market. It incorporates OPTIQ as an exposure control software. OPTIQ includes the CNR software version and the ULD organ dose program that were refined and validated during this investigation. Detailed information about the study workflow can be found in Fig 1.

Pretests (water-equivalent phantom and PMMA phantom). To understand the technical parameters, the HOR environment (Table I) was characterized. Before this study, qualitative tests for different software and hardware settings were performed on a water-equivalent phantom (water tank). This strategy included settings of ARTIS pheno and exposure control software (CNR adaption to surgeons ALARA preferences) resulting in an ULD mode (see Appendix). Second, the impact of collimation and digital magnification on DAP during digital subtraction angiography (DSA) and fluoroscopy were quantified using a polymethyl methacrylate (PMMA) phantom (16.6 \times 30 \times 30 cm; height \times width \times length). A maximum source image receptor distance of 110 cm was used, and the initial magnification by digital zoom was 42 cm. An average of four measurements (15 seconds each) were taken for each evaluated step. The customized setup comprised two frames per second in fluoroscopy mode and four frames per second in DSA mode. While striving to reduce radiation dose, adjustments were to leave image quality unaltered. Within the exposure control software algorithm, the image quality parameter is defined as CNR on the output image. Different scan modes were evaluated (factory setup, lowdose setup, /ULD setup) in addition to the use of digital magnification (reference 42 cm, tested 50, 42, 32, 22, and 16 cm) and collimation. Cumulative air kerma (in mGy), and DAP in Gy·cm² were recorded. Once the effects of the parameters were studied, adjustments to imaging settings were made and implemented into ULD-SOP.

EVAR protocol (prSOP/ULD-SOP). Standard EVAR has been performed formerly with prSOP and HOR manufacturer predefined software setup. prSOP defines the order of manual steps, their technical application, and the imaging steps during standard EVAR (Table II). To develop ULD-SOP, first, the predefined software setup was evaluated and refined by the pretests of this study.

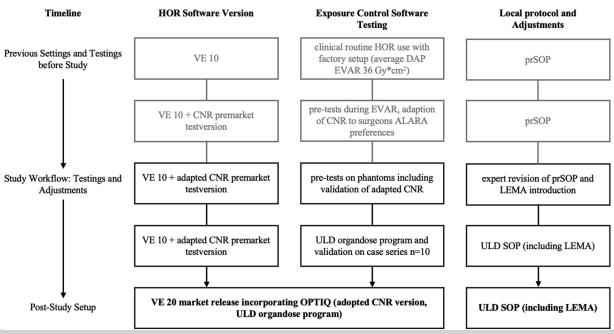


Fig 1. Study workflow embedded into the timeline of hybrid operating room (*HOR*) setup evolution. *ALARA*, as low as reasonably achievable; *CNR*, contrast-to-noise ratio; *EVAR*, endovascular aortic repair; *LEMA*, Lucerne endovascular aortic repair milestone approach; *prSOP*, previous surgical standard operating protocol; *SOP*, standard operating protocol; *ULD*, ultra-low-dose.

Then, results regarding surgical steps were transferred with expertise of local endovascular surgery senior experts to the new ULD-SOP with respect to strict ALARA.

LEMA. LEMA comprises the whole surgical workflow from preoperative planning to postoperative follow-up (Table III). LEMA also aims to standardize education for surgical residents and enable benchmarking for radiation dose during endovascular surgery.

Study design and patient cohort. The local ethics committee of the region approved this prospective feasibility study cohort (REQ-2023-00,705). Ten consecutive patients undergoing EVAR in our university teaching and research hospital between August 2020 and January 2021 were included. Informed consent was obtained from all patients. Inclusion criteria were elective indication for EVAR according to current guidelines and low and medium anatomical complexity suited for standard EVAR.²¹ Detailed information about inclusion and exclusion criteria can be found in Table IV.

EVAR was performed primarily using the trimodular TREO Endograft (Terumo Aortic, Bolton Medical Inc., Sunrise, FL; standard device in our institution) by four different vascular surgeons, all certified in radiation safety. Contrast agent was administered in a one-to-one ratio with saline solution, with each shot containing 12.5 mL of contrast agent.

Primary and secondary outcome parameters. The primary outcome parameters were DAP (in Gy·cm²,

obtained from the structured system dose report) and achievement of ULD defined as a DAP of <10 Gy·cm². Secondary outcomes included fluoroscopy time (in minutes:seconds), cumulative air kerma (in mGy), and clinical success as defined by the Society for Vascular Surgery Reporting Standards. Clinical success implies technical success paired with treatment success and the absence of mortality or severe perioperative morbidity.²²² The distance between the proximal beginning of the endoprosthesis fabric and the vascular orifice of the lower kidney artery was assessed for surgical accuracy. Completion follow-up comprised time between surgery and 1-year follow-up computed tomography (CT) scan with respect to guidelines.²³ Regarding LEMA, DAPs for each milestone were included.

Data management. Diameter and determinations regarding distances as well as the assessments of endoleaks were carried out in the postoperative CT scan and using MERLIN Diagnostic Workcenter (Phönix PACS GmbH, Freiburg im Breisgau, Germany). For data extraction, the electronic medical record system EPIC (Epic Systems Corporation, Verona, WI) was used. Data were collected in an Excel spreadsheet (Microsoft, Redmond, WA) and used for further calculation.

Statistical analysis. Statistical analysis was also performed in Excel. Continuous variables were described as means with standard deviation or medians with interquartile ranges, as well as minimal and maximal values.

Table I. Hybrid operating room (HOR) environment

Components	Specification	Manufacturer description	
Floor-mounted robotic C-arm	Artis pheno	Nine degrees of freedom supporting flexible positioning and wide reach of C-arm, 2D and 3D imaging in virtually any patient position, freely adjustable working height for 2D imaging, 3D imaging possible even with a tilted table top.	
Software version	VE10	Manufacturer setup.	
Exposure control software	VE10 plus modified CNR	Premarket test version of contrast-based technique, supported by intelligent, self-adjusting algorithms, automatically considers source image receptor distance, collimation settings, grid status, and patient thickness to find and apply best suitable combination of the five radiation exposure parameters and the detector dose as an additional variable.	
Exposure control software	VE20 plus OPTIQ	Commercially available version of VE10 upgrade including findings of this study regarding exposure control software.	
Live 3D endovascular guidance system	EVAR 3D Guidance	Overlay of 3D information on top of live fluoroscopy to deliver optimized C- arm angulations, precise 3D overlay and guidewire and catheter navigation	
2D, Two-dimensional; 3D, three-dimensional; CNR, contrast-to-noise ratio; EVAR, endovascular aortic repair.			

RESULTS

Pretests: Water-equivalent and PMMA phantom. Pretests were first carried out on water-equivalent phantom for adjustment and then validated on a PMMA phantom. Based on the water-equivalent phantom pretests, settings of the CNR exposure control software were adapted to surgeons' ALARA preferences. Parameters were then reproduced and validated by the PMMA phantom. Three different imaging protocols (factory, low-dose, and ULD setups) for exposure control software were compared in fluoroscopy and DSA modes.

For fluoroscopy, the factory setup results were 0.3 Gy·cm² per minute, low-dose setup results were 0.04 Gy·cm² per minute, and ULD setup results were 0.0382 Gy·cm² per minute. For DSA, factory setup results were 2.48 Gy·cm² per minute, low-dose setup results were

Table II. Previous surgical standard operating protocol (prSOP)

	Traditional standard EVAR protocol		
Preoperative	Preoperative planning		
a.	Choice of procedure		
b.	Preoperative device selection and sizing		
C.	Definition of beam angulations for parallaxes correction		
d.	Implantation order and access method (percutaneous or cut down)		
e.	Selection of imaging software mode (standard was low dose)		
Intraoperativ	Intraoperative		
f.	2D/3D registration for fusion imaging		
g.	Intraoperative use of EVAR 3D guidance		
h.	Strict definition of DSA sequences		
i.	Minimal detector distance		
j.	Beam angulations as much as reasonable		
k.	Avoid magnification		
I.	Maximum collimation		
m.	Ballooning of landing and overlap zones (1 or 2 balloons)		
$\ensuremath{\mathit{3D}}\xspace$. Three-dimensional: $\ensuremath{\mathit{DSA}}\xspace$, digital subtraction angiography: $\ensuremath{\mathit{EVAR}}\xspace$, endovascular aortic repair.			

2.42 Gy·cm 2 per minute, and ULD setup results were 2.36 Gy·cm 2 per minute.

Fig 2 shows the obtained impact of magnification on DAP. By using digital magnification, DAP could be reduced by \leq 79% (for a 16-cm field of view) with respect to the reference setup of a 42 cm field of view. Furthermore, the use of collimation reduced DAP and scattered radiation proportional to the reduction in the imaged area.

EVAR protocol (prSOP/ULD-SOP). Deriving results from pretests, we applied changes to prSOP for standard EVAR to introduce ULD-SOP. Concerning the steps of prSOP, steps a to d remained unaffected. For step e, the ULD software mode was designated as the new standard setting for imaging. Steps f to h remained unchanged. Additionally, a dose guy was introduced to supervise radiation dose usage. The operating teams consist of a junior and a senior vascular surgeon, and the role of the dose guy is always taken by the senior surgeon. The dose guy's responsibility is to intervene during the EVAR procedure to address aspects for radiation reduction, such as use of the correct dose software setup, collimation, or zoom. Use of digital magnification is recommended as much as reasonable. For persistent endoleaks type I or III, ballooning of landing and overlap zones was now performed routinely with two balloons to avoid recurrent angiographies.

Table III. Lucerne endovascular aortic repair (EVAR) milestone approach (LEMA)

Time point	Steps	Settings and recommendations
Preoperatively	 Decision-making: strategic conceptualization based on patient demographics, comorbidities and anatomy (choice of procedure) Planning and device sizing: planning procedure based on CT scan (device type/length/diameter/positioning, landing zones, ostia rings, beam angulations for parallaxes correction), implantation order and access method (percutaneous or cut down) 	
Intraoperatively	 2D/3D Registration: two 90° fluoroscopy images merged with 3D preoperative CT image Re-registration: after insertion of wire and stent readjustment of the overlay to the actual anatomy to reach real time roadmap End of cannulation contralateral leg: end of contralateral leg cannulation with full deployment (cumulated dose of fluoroscopy images and DSA sequences measured) Full deployment and completion DSA: end of deployment of main body and ipsilateral leg (cumulated dose of fluoroscopy image and DSA sequences measured) Cone beam CT (optional): mostly used in fenestrated and branched EVAR procedures, not in standard EVAR procedures 	 Imaging software mode ultra low dose Use of EVAR 3D guidance Strict definition of DSA sequences Maximize digital magnification and collimation Reduce detector distance and beam angulation Attendance of a dose guy Two ballons for landing and overlap zones
Postoperative	Postoperative control: reference for further follow up, control CTA (with or without contrast-enhanced ultrasound)	
2D, Two-dimension	al; 3D, three-dimensional; CT, computed tomography.	

LEMA. The ULD-SOP was organized in a new shape and embedded into LEMA. LEMA consists of eight milestone steps, five of which are intraoperative. It enables standardization of EVAR planning and implantation in the HOR and allows for systematized reporting and stepwise benchmarking of dose application (dose check points at the end of each intraoperative milestone). For the full view of LEMA (including ULD-SOP), see Table III. During the case series, LEMA enabled the collection of detailed dose information.

Case series: Patient characteristics. Ten consecutive patients out of 43 planned EVARs were suitable for enrolment. Nine patients were male (90%), mean age was 70.3 \pm 6.4 years, and the mean body mass index was $26.1 \pm 4.2 \text{ kg/m}^2$. Minimum proximal landing zone was 14 mm (14-42 mm), maximum aneurysm sac diameter was 59 mm (37-59 mm). All indications were set according to current guidelines. Seven patients were indicated for surgery owing to aneurysm diameter primarily. Three patients presented with an aortic aneurysm diameter below threshold, including one patient presenting with abdominal pain during palpation and two patients with aneurysmatic configurations owing to plaque rupture with rapid diameter progression (>1 cm in 6 months). For nine patients (90%) a TREO stent graft was used, and one patient (10%) received a Gore Excluder stent graft (W. L. Gore & Associates, Inc., Newark, DE). For detailed patient characteristics including anatomical measures of the aneurysm, see Table V.

Table IV. Inclusion and exclusion criteria for patient selection

Inclusion criteria	Exclusion criteria
Elective surgery	Emergency cases
Infrarenal aortic aneurysm	High anatomical complexity ^a
Mild to moderate anatomical complexity ^a	Hostile neck anatomy ^b
Age >18	Access side problems
Legal capacity of patient to agree to surgery	Concomitant vascular lesions (eg, iliac aneurysm)
Endovascular approach with standard three modular device	Infections of patient

^aTzanis E, Ioannou CV, Tsetis D, et al. Complexity-based local diagnostic reference levels (DRLs) for standard endovascular aneurysm repair (EVAR) procedures. *Phys Med* 2020; 73:89-94.

^bAntoniou GA, Georgiadis GS, Antoniou SA, et al. A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy. *J Vasc Surg* 2013; 57(2):527-38.

Primary outcomes. The median DAP was 5.6 Gy·cm² ranging from 3.54 to 12.10 Gy·cm². ULD EVAR was achieved in eight patients (80%). Individual DAP for each patient with respect to fluoroscopy time is presented in Table VI.

Secondary outcomes. The median fluoroscopy time was 16 minutes 32 seconds (7 minutes 42 seconds to

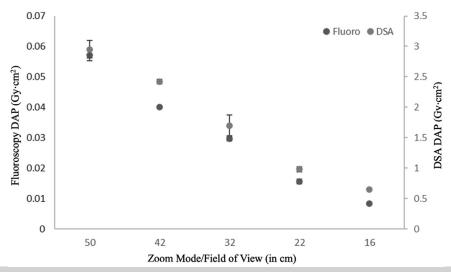


Fig 2. Impact of digital zoom on dose area product (*DAP*) for fluoroscopy and digital subtraction angiography (*DSA*) during phantom pretests.

Table V. Patient characteristics (n = 10)

Table V. Patient Characteristics (II = 10)			
	Mean (min-max)		
Age, years	70.3 (61.0-79.0)		
Weight, kg	84.05 (59.5-105.0)		
Height, m	1.77 (1.59-1.89)		
BMI, kg*m2	26.70 (21.90-34.16)		
Proximal landing zone length, mm	30 (14-42)		
Iliac landing zone length right, mm	59.7 (15.0-90.0)		
Iliac landing zone length left, mm	61.9 (45.0-84.0)		
Lower kidney to fabric distance, mm	3.5 (0.0-15.0)		
Diameter of AAA, mm, median (IQR)	51 (8.75)		
Diameter of neck, mm	20.2 (15.0-24.0)		
AAA, Abdominal aortic aneurysm; BMI, body mass index; IQR, interquartile range.			

25 minutes 43 seconds). Clinical success was achieved in all patients (n = 10). The mean distance between fabric and vascular outlet of lower kidney artery was 3.5 mm. There were no type I or III endoleaks. Type II endoleaks were present in five cases, with retrograde inflow from the inferior mesenterial artery (n = 3) and lumbal arteries (n = 3). Two patients had an endoleak type II resulting from retrograde inflow of both arteries. In one case, a type II endoleak via A. circumflexa ilium profunda on both sides was present. During hospitalization owing to EVAR, one patient experienced perforation of a previously reported sigma diverticulitis. According to histopathological results of resected intestine, there was no evidence of affected microperfusion or major sigmoid ischemia. All patients completed 1-year follow-up CT scans. Detailed information on outcomes can be found in Table VII. Regarding LEMA, Milestone 5 covering insertion and deployment of the main body and the

contralateral leg has been responsible for 2.23 Gy·cm², representing almost 40% of DAP for the procedure. Detailed dose information for each milestone can be found in Table VIII.

DISCUSSION

Aortic endovascular procedures, including the use of fenestrated and branched endoprostheses, are now widely adopted. Dose reduction during endovascular procedures is an important challenge, addressed through SOP-based, optimized and accurate implantation procedures, facilitated by navigation aids and additive methods such as FORS or IVUS examination. This study aims to demonstrate reduced radiation intensity during application, emphasizing the need for standardized reporting.

The reduction of radiation dose in endovascular surgery ensures health protection for patients and staff and serves as a surrogate marker for process quality.¹³ This study demonstrates that standard EVAR procedures with ULD defined as a DAP of <10 Gy·cm² are possible routinely. These values apply to standard interventions for abdominal aortic aneurysm with a simple and moderate difficulty level in a modern HOR.²¹ A differentiated workflow and benchmarking system (LEMA) was applied to reduce and evaluate radiation dose. Prerequisites for the workflow underlying this study included the analysis of technical conditions (pretests on a phantom model), software adjustments, adaptation of the workflow to technical specifications, team training, and education.

HOR environment. Medical technology companies have developed variables for dose reduction requiring consideration during surgery. This study showed that digital magnification in the HOR significantly reduced dose compared with magnification options of

Table VI. Individual dose area product (*DAP*) and fluoroscopy time

товсору сите		
Patient	DAP, Gy·cm²	Fluoroscopy time, minutes:seconds
1	4.71	08:10
2	9.21	11:59
3	7.01	18:57
4	3.57	17:17
5	12.1	11:46
6	5.99	15:20
7	3.54	19:30
8	5.2	25:43
9	11.1	19:24
10	4.21	07:42

predecessor models or conventional devices. Adjustments of software parameters reduced radiation dose during fluoroscopy by 54% and during DSA by 91%. The applied ULD software setting was previously adjusted and tested with the medical technology company. These aspects underline the influence of the surgical workflow on dose and thus its importance for radiation reduction. For instance, as shown in this study, DSA can be used very gently and without a loss of quality during implantation, as well as for final on-table imaging while complying with ULD and ALARA. Reducing angulation and radiation duration, along with understanding imaging technology, are crucial for successfully implementing ULD.

Evaluation of dose levels. The use of radiation in endovascular surgery is increasingly investigated by the vascular scientific community. Different parameters such as fluoroscopy time, DAP, or skin dose for the evaluation of radiation dose are widely spread. 12,24 In addition, the physical units are often specified differently (DAP units).^{12,25} Consequently, this process leads to a data situation hardly allowing comparison and prone to misunderstandings in dose reporting. Previous analyses also indicate a wide range of reported dose levels for vascular surgical interventions.¹³ Furthermore, some reports include interventions with very distinct difficulty levels or several types of procedures.²⁶ Differentiating the peculiarities of surgical methods in terms of radiation intensity is thus hardly possible. A recently introduced complexity indices classification for EVAR procedures suggested 144.2 Gy·cm² as the diagnostic reference level (DRL) for low complexity interventions.²¹ In some countries, regulations or guidelines exist regarding dose ranges that should be adhered to as upper limits per procedure.²⁷ These DRLs are based on relevant but older studies, highlighting the relevance on continually updated exposure information.^{24,28,29} Consequently, corresponding guidelines and thus the

Table VII. Primary and secondary outcomes (n = 10)

	Mean (minimum to maximum) or number (%)
DAP, Gy·cm ²	5.60 (3.54 to 12.10)
Fluoroscopy time, minutes:seconds	16:32 (7:42 to 25:43)
Clinical success	10 (100)
Endoleak Type I	0
Endoleak type II	5 (50)
Endoleak type III	0
Ultra low DAP	8 (80)
DAP, Dose area product.	

Table VIII. Dose area product (*DAP*) with regard to Lucerne endovascular aneurysm repair milestone approach (*LEMA*) milestones

LEMA milestone	Median DAP, Gy·cm ²	Minimum DAP, Gy·cm²	Maximum DAP, Gy·cm²
3. 2D/3D registration	0.63	0.03	0.94
4. Re-registration	1.65	0.67	2.99
5. End of cannulation contralateral leg	2.23	1.12	4.58
6. Full deployment and completion DSA (end of procedure)	1.09	1.72	3.59
Cumulative DAP	5.60	3.54	12.10
DSA, Digital subtraction angiography.			

protection of patients and staff from increased radiation exposure depend on a continually updated database in literature.

LEMA for benchmarking. In this study, a reporting and benchmarking protocol was designed and applied, dividing the procedure into different milestones. This benchmarking is intended to provide several benefits. By gathering dose data continuously during the intervention, the respective procedure can be compared at each intraoperative milestone with the designated benchmark. This process allows an early estimate of whether the procedure's radiation dose falls within the intended corridor for the final DAP. Deviations might serve as early indicators of either faulty adjustments of technical parameters or unplanned proceedings of the procedure. In both cases, corrections or optimizations of settings are indicated and necessary regarding ALARA. Furthermore, benchmarking enables a comparison of surgeons' performance and quality of surgical workflow not only within a center, but also across various institutions. By division into milestones, comparability between different types of procedures is also facilitated. For

instance, the DAP for an additional cone beam CT scan can be deducted specifically, and the remaining procedure can then be compared within a pool of EVAR interventions. Also, comparison of different imaging systems is possible through LEMA.

LEMA for standardization and workflow optimization. The prerequisite for LEMA is a highly standardized procedural flow including ULD-SOP. Since the choice of method and implementation of the procedure (eg, a two-modular or tri-modular system) influences dose and intraoperative course, these are also embedded into LEMA. Planning of execution, including beam angulations during surgery, evaluation of landing zone use, and considerations regarding DSA duration are crucial for dose. This also comprises navigation program application with an overlay function (syngo EVAR Guidance, Siemens Healthineers, Forchheim, Germany) producing an intraoperative maximum DSA projection image, as an important dose saving module. Its use also requires thorough preoperative planning and parameter selection.

Predefined imaging parameters were assigned to each milestone enabling comparability among surgeons. This highly standardized course facilitates comparability, especially for standard interventions. The strength lies in standardization of intervention as a basis for resident education, evaluation of equipment settings, and reproducibility. Complex interventions require an adapted approach, because principles can be transferred, but their workflow steps cannot be as rigidly standardized as for standard EVAR. Through the adjustment of our imaging parameter settings and strict use of LEMA, the radiation dose for standard EVAR in our institution could be reduced by 86% from 40 Gy·cm² to approximately 5.5 Gy·cm² with lowest reported DAP of 2.4 Gy·cm² in a single case.³⁰

LEMA for education. With the introduction of LEMA, the impact of technical settings and equipment conditions as well as their application during EVAR can be trained precisely. The objective is to integrate individual benchmarking into training protocols, facilitating adaptation of the HOR environment as a natural surrounding during initial phases of surgeon's education.

For future generations of vascular surgeons, the focus will shift from feasibility of procedures towards their precision and automation. Therefore, the HOR environment with its equipment and technical conditions is an essential surrounding and knowledge of the associated mechanisms should be an indispensable part of vascular surgeon's education. Thus, the purpose of LEMA is not to compete for lowest radiation dose. Instead, the focus is on assessment of the use of radiographs in aortic surgery. LEMA can also serve as a learning foundation for complex procedures, even if these are not suitable for highly standardized workflows.

Alternatives. The presented approach is specific to the outlined surgical and technical environment and workflows of our institution. Radiation savings can be achieved in HORs from other manufacturers or through numerous other means, also depending on the conditions of the respective facility and the operators' knowledge of their mechanisms. LEMA aims at radiation avoidance in the best ALARA sense. Radiation avoidance can thus be seen a result of good planning, precise preparation, experience, education, and technical environment.^{17,14} The use of transcutaneous duplex ultrasound examination, IVUS examination, or the recently introduced fiberoptic navigation are additional options that have yet not been incorporated into our concept. However, even with using FORS technology in a specialized endovascular center, average DAP for EVAR was 102.7 Gy·cm^{2,31}

Outlook. Radiation will become an increasingly considered parameter in endovascular surgery, assessing procedural quality not only for patients but especially for staff. Their radiation protection and thus occupational health must be a significant motivator for radiation exposure reduction. In more standardized procedures, radiation exposure is particularly measurable and comparable, thus serving as an important surrogate parameter in the thoroughness of implementation. By benchmarking individual surgical steps, effects of innovations and strategies can be assessed. Deviations from predefined benchmarks can also facilitate solving intraoperative obstacles. In the future, broadly gathered data for milestones have the potential to be applied by official institutions for DRL forming, or in context of centralization and allocation of procedures to specific centers. Standardization is also a crucial requirement towards desired automation of endovascular procedures.

CONCLUSIONS

Currently, the focus in endovascular aortic surgery is on issues regarding optimization in various process areas. These issues include navigation, prosthesis design, and radiation reduction. ULD can be achieved routinely according to the present and other studies, but requires technical knowledge, process protocols, and education. A key future topic could be automation of the procedure and similar measures for complex endovascular aortic procedures.

FUNDING

None.

DISCLOSURES

M.H. is a consultant for Siemens Healthineers and Member of an Advisory Board for Siemens Healthineers.

The authors thank Dirk Sunderbrink and colleagues (Siemens Healthineers AG, Forchheim, Germany) for their

support in optimizing the application protocols and in carrying out parts of the examinations on the phantom model.

REFERENCES

- Dake MD, Miller DC, Semba CP, Mitchell RS, Walker PJ, Liddell RP. Transluminal placement of endovascular stent-grafts for the treatment of descending thoracic aortic aneurysms. N Engl J Med. 1994;331:1729–1734.
- Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. *Ann Vasc Surg.* 1991;5: 491–499.
- Anderson JL, Berce M, Hartley DE. Endoluminal aortic grafting with renal and superior mesenteric artery incorporation by graft fenestration. J Endovasc Ther. 2001;8:3–15.
- Stanley BM, Semmens JB, Lawrence-Brown MM, Goodman MA, Hartley DE. Fenestration in endovascular grafts for aortic aneurysm repair: new horizons for preserving blood flow in branch vessels. J Endovasc Ther. 2001;8:16–24.
- Yaoguo Y, Zhong C, Lei K, Yaowen X. Treatment of complex aortic aneurysms with fenestrated endografts and chimney stent repair: systematic review and meta-analysis. Vascular. 2017;25:92–100.
- Patel AP, Gallacher D, Dourado R, et al. Occupational radiation exposure during endovascular aortic procedures. Eur J Vasc Endovasc Surg. 2013;46:424–430.
- Williamson AJ, Babrowski T. Current endovascular management of complex pararenal aneurysms. J Cardiovasc Surg. 2018;59:336–341.
- Suckow BD, Goodney PP, Columbo JA, et al. National trends in open surgical, endovascular, and branched-fenestrated endovascular aortic aneurysm repair in Medicare patients. J Vasc Surg. 2018;67: 1690–1697.e1.
- Kirkwood ML, Guild JB, Arbique GM, Anderson JA, Valentine RJ, Timaran C. Surgeon radiation dose during complex endovascular procedures. J Vasc Surg. 2015;62:457

 –463.
- Schanzer A, Steppacher R, Eslami M, Arous E, Messina L, Belkin M. Vascular surgery training trends from 2001-2007: a substantial increase in total procedure volume is driven by escalating endovascular procedure volume and stable open procedure volume. *J Vasc Surg.* 2009;49:1339–1344.
- Hertault A, Maurel B, Sobocinski J, et al. Impact of hybrid rooms with image fusion on radiation exposure during endovascular aortic repair. Eur J Vasc Endovasc Surg. 2014;48:382

 –390.
- Tuthill E, O'Hora L, O'Donohoe M, et al. Investigation of reference levels and radiation dose associated with abdominal EVAR (endovascular aneurysm repair) procedures across several European Centres. Eur Radiol. 2017;27:4846—4856.
- Hertault A, Bianchini A, Amiot S, et al. Editor's choice Comprehensive literature review of radiation levels during endovascular aortic repair in cathlabs and operating theatres. Eur J Vasc Endovasc Surg. 2020;60:374–385.
- Modarai B, Haulon S, Ainsbury E, et al. Editor's choice European Society for Vascular Surgery (ESVS) 2023 clinical practice guidelines on radiation safety. Eur J Vasc Endovasc Surg. 2023;65:171–222.
- Rolls AE, Rosen S, Constantinou J, et al. Introduction of a team based approach to radiation dose reduction in the enhancement of the Overall radiation safety profile of FEVAR. Eur J Vasc Endovasc Surg. 2016;52:451–457.

- Image Wisely Initiative. American College of Radiology: 2023. Accessed September 21, 2024. https://www.imagewisely.org/About-Us.
- van den Haak RF, Hamans BC, Zuurmond K, Verhoeven BA, Koning OH. Significant radiation dose reduction in the hybrid operating room using a Novel X-ray imaging technology. Eur J Vasc Endovasc Surg. 2015;50:480–486.
- Sailer AM, de Haan MW, Peppelenbosch AG, Jacobs MJ, Wildberger JE, Schurink GW. CTA with fluoroscopy image fusion guidance in endovascular complex aortic aneurysm repair. Eur J Vasc Endovasc Surg. 2014;47:349–356.
- El-Sayed T, Patel AS, Cho JS, et al. Radiation-induced DNA damage in operators performing endovascular aortic repair. *Circulation*. 2017;136:2406–2416.
- Lipsitz EC, Veith FJ, Ohki T, et al. Does the endovascular repair of aortoiliac aneurysms pose a radiation safety hazard to vascular surgeons? J Vasc Surg. 2000;32:704—710.
- Tzanis E, Ioannou CV, Tsetis D, Lioudaki S, Matthaiou N, Damilakis J. Complexity-based local diagnostic reference levels (DRLs) for standard endovascular aneurysm repair (EVAR) procedures. *Phys Med.* 2020;73:89–94.
- Oderich GS, Forbes TL, Chaer R, et al. Reporting standards for endovascular aortic repair of aneurysms involving the renalmesenteric arteries. J Vasc Surg. 2021;73:45–52S.
- Moll FL, Powell JT, Fraedrich G, et al. Management of abdominal aortic aneurysms clinical practice guidelines of the European Society for Vascular Surgery. Eur J Vasc Endovasc Surg. 2011;41(Suppl 1): S1–S58.
- Rial R, Vano E, Del Rio-Sola ML, et al. National diagnostic reference levels for endovascular aneurysm repair and optimisation strategies. Eur J Vasc Endovasc Surg. 2020;60:837–842.
- Jones C, Badger SA, Boyd CS, Soong CV. The impact of radiation dose exposure during endovascular aneurysm repair on patient safety. J Vasc Surg. 2010;52:298–302.
- Dias NV, Billberg H, Sonesson B, Tornqvist P, Resch T, Kristmundsson T. The effects of combining fusion imaging, lowfrequency pulsed fluoroscopy, and low-concentration contrast agent during endovascular aneurysm repair. J Vasc Surg. 2016;63: 1167, 1165.
- Strahlenschutz Bf. 2023. Accessed September 21, 2024. https://www.bfs.de/SharedDocs/Downloads/BfS/DE/fachinfo/ion/drw-roentgen.pdf;jsessionid=E098ADE919322EA7C86093C244296EE9.2_cid374?_blob=publicationFile&v=11.
- Schegerer A, Loose R, Heuser LJ, Brix G. Diagnostic reference levels for diagnostic and interventional X-ray procedures in Germany: update and handling. *Röfo*. 2019;191:739–751.
- Kanda R, Akahane M, Koba Y, et al. Developing diagnostic reference levels in Japan. Jpn J Radiol. 2021;39:307

 –314.
- Reeg A, Braun Y, Sunderbrink D, Hakimi M. Lowest reported dose area product of 2.4 Gy *cm(2) for ultra-low-dose endovascular aortic aneurysm repair of a standard infrarenal aortic aneurysm. J Vasc Surg Cases Innov Tech. 2024;10:101496.
- **31.** Panuccio G, Schanzer A, Rohlffs F, et al. Endovascular navigation with fiber optic RealShape technology. *J Vasc Surg.* 2023;77:3–8.e2.

Submitted Sep 26, 2024; accepted Nov 25, 2024.

Additional material for this article may be found online at www.jvscit.org.