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Development and assessment of case-specific physical and augmented reality simulators for intracranial aneurysm clipping

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Abstract

Background Microsurgical clipping is a delicate neurosurgical procedure used to treat complex Unruptured Intracranial Aneurysms (UIAs) whose outcome is dependent on surgeon's experience. Simulations are emerging as excellent complements to standard training, but their adoption is limited by the realism they provide. The aim of this study was to develop and validate a microsurgical clipping simulator platform.

Methods Physical and holographic simulators of UIA clipping have been developed. The physical phantom consisted of a 3D printed hard skull and five ($n=5$) rapidly interchangeable, perfused and fluorescence compatible 3D printed aneurysm silicone phantoms. The holographic clipping simulation included a real-time finite-element-model of the aneurysm sac, allowing interaction with a virtual clip and its occlusion. Validity, usability, usefulness and applications of the simulators have been assessed through clinical scores for aneurysm occlusion and a questionnaire study involving 14 neurosurgical residents (R) and specialists (S) for both the physical (p) and holographic (h) simulators by scores going from 1 (very poor) to 5 (excellent).

Results The physical simulator allowed to replicate successfully and accurately the patient-specific anatomy. UIA phantoms were manufactured with an average dimensional deviation from design of 0.096 mm and a dome thickness of 0.41 ± 0.11 mm. The holographic simulation executed at 25–50 fps allowing to gain unique insights on the anatomy and testing of the application of several clips without manufacturing costs. Aneurysm closure in the physical model evaluated by fluorescence simulation and post-operative CT revealed Raymond 1 (full) occlusion respectively in 68.89% and 73.33% of the cases. For both the simulators content validity, construct validity, usability and usefulness have been observed, with the highest scores observed in clip selection usefulness $R_p=4.78$, $S_p=5.00$ and $R_h=4.00$, $S_h=5.00$ for the printed and holographic simulators.

Conclusions Both the physical and the holographic simulators were validated and resulted usable and useful in selecting valid clips and discarding unsuitable ones. Thus, they represent ideal platforms for realistic patient-specific simulation-based training of neurosurgical residents and hold the potential for further applications in preoperative planning.

Keywords Unruptured intracranial aneurysms, Simulator, Microsurgical clipping, Neurosurgery, Augmented reality, Surgical Training, Preoperative Planning

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Background

Unruptured Intracranial Aneurysms (UIA) represent one of the most common neurovascular pathologies with a prevalence of 3% worldwide [1]. These rupture-prone lesions consist of focal dilations of cerebral arteries and account for 85% of non-traumatic subarachnoid haemorrhages, associated with poor outcomes in 35% of the cases [2]. Their management can be conservative (best medical treatment), or interventional through microsurgical Aneurysm Clipping (AC) or by application of Endovascular Techniques (EVT) [3]. Technical advancements led to an increasingly competitive situation between neurosurgeons and interventionalists, and to a shift towards an increasing number of EVT cases [4]. Simultaneously, as the number of AC cases is diminishing, a trend has been observed toward more complex UIAs – not amenable to established endovascular modalities – being referred to cerebrovascular neurosurgeons [5]. As surgical experience and caseload correlate with clinical and radio-anatomical outcomes, this decreasing number of microsurgically treated UIAs poses a challenge for the training of future neurosurgeons. Consequently, an increasing demand for cost-effective training methods able to reproduce the complexities related with AC and EVT, preferably in a single embedded solution, has been reported [6].

Emerging technologies like Additive Manufacturing (AM), Augmented Reality (AR) and Virtual Reality (VR) found a variety of applications in medicine, especially in cerebrovascular simulation [6–8]. Tools for training, preoperative planning, intraoperative support and post-operative evaluation have been developed [9, 10]. Bench simulators have been increasingly employed, providing reproducible and comparable training sessions, even though most of these devices or techniques were limited in terms of visual and physical realism, case-specificity, and haptic realism [11]. Different studies aimed at the realization of highly accurate rigid 3D models; [12–17] others employed soft materials to produce hollow and case-specific aneurysm models for EVT or clipping simulation; [18–24] numerous approaches focused on the development of whole case-specific head simulators, but with tedious and expensive production processes [14, 25–32]. Overall, these studies share a limited mechanical behaviour or, unfortunately, a lack of implementation in clinical routine. Digital simulations of AC integrating Finite Element Modelling (FEM) have been developed to have instruments controlled through haptic devices and VR or 2D/3D monitors visualization [33–35]. AR has been used in neurovascular surgery, predominantly as a passive method to overlay information on the real world, thus having the potential of serving both as a technology for training and intraoperative support [36–39]. To

the best of the authors' knowledge, simulators integrating affordable 3D printed simulators as well as holographic AR and real-time FEM simulation are missing. This study complements the research conducted and reported by Dodier et al. [40], with the aim of reporting the simulators development, and to validate them in terms of their usefulness and possible applications.

Methods

Cases selection, segmentation and models preparation

This research study was approved by the institutional ethical commission of Medical University of Vienna (Nr. 1593/2021). Five UIAs cases previously treated with AC have been selected to reflect the variability of different arterial locations (Anterior Communicating Artery (AComA), Internal Carotid Artery (ICA) and Middle Cerebral Artery (MCA)), different approaching side (left and right) and different craniotomies (pterional and extended pterional/fronto-temporal). Preoperative images of the selected cases (Digital Subtraction Angiography (DSA), Computer Tomography (CT) and Magnetic Resonance Images (MRI)) have been segmented in Materialise Mimics 23.0 (Materialise, Belgium) and 3D Slicer to extract the volumes of brains, skulls and vessels [41]. Subsequently, the digital model of a generic skull (20×27×28 cm) and a generic brain have been acquired and registered, and the two large overlapping craniotomies have been incised on both left and right sides of the skull in Meshmixer 3.5 (Autodesk, CA, USA) [42]. A replica of a general clip applicator has been designed in the CAD software Fusion 360 (Autodesk, California, USA), and 11 different commercial clips were scanned in a MicroCT with an isotropic slice thickness of 30 μm (μCT 50, Scanco Medical, Switzerland) and segmented to obtain their digital models. The segmented models of vessels and skulls of the selected cases have been imported in Materialise 3-Matic 15.0 (Materialise, Belgium) and rigidly registered on the generic skull and brain. In each case-specific vascular model, the aneurysms were isolated from the adjacent vasculature. Due to the limitations of the available imaging techniques, it was not possible to accurately determine the precise wall thickness distribution of the aneurysm sacs. Consequently, a uniform wall thickness was assumed and set to 0.4 mm in Meshmixer 3.5 by using the offset computation tool. The chosen value of 0.4 mm was determined to optimally balance between realistic representation of thickness and manufacturability constraints.

Physical simulator

Design and parts printing

Designing the physical simulator started from the case-specific aneurysms, for which tailored housings have

been developed in order to support them and their parent arteries, allow their perfusion and geometrically lock on the generic skull (Fig. 1A, B). The generic skull, with exclusion of the occipital bone, and the housings have been manufactured with the 3D printer Formlabs 2 (Formlabs, MA, USA) using the resin White V2 and imposing an internal lattice structure in order to reduce model weight and costs. Silicone 3D printing has been employed for the production of the case-specific aneurysms. This manufacturing method has been selected because it allows to print hollow samples with a wall thickness value down to 0.2 mm, considered realistic with respect to real aneurysm sac measurements [43, 44]. Additionally, the compatible material TrueSil 20 A (Young Modulus >0.25 MPa; Hardness Shore

A=20; Tensile strength=4.3 MPa; Elongation=815%; Tear strength=5.8 N/mm; SpectroPlast, Switzerland) [45] has been selected for its mechanical properties that best mimic aneurysm sac biomechanics (Young Modulus \approx 1 MPa; Hardness Shore A <25; Tensile strength \approx 2 MPa; Elongation \approx 600%) [43]. Its transparency makes it a good candidate to use liquids of different colour and mimic ICG-VA. The printed parts have then been MicroCT scanned (isotropic spatial resolution=207 μ m), and the obtained models have been compared with the original designs in MeshLab with the tool Align. Secondly, the thickness of the aneurysm sac was assessed in Materialise 3-Matic with the Thickness analysis tool. Finally, the aneurysms have been introduced in the housings and connected to extension lines allowing their perfusion (Fig. 1C).

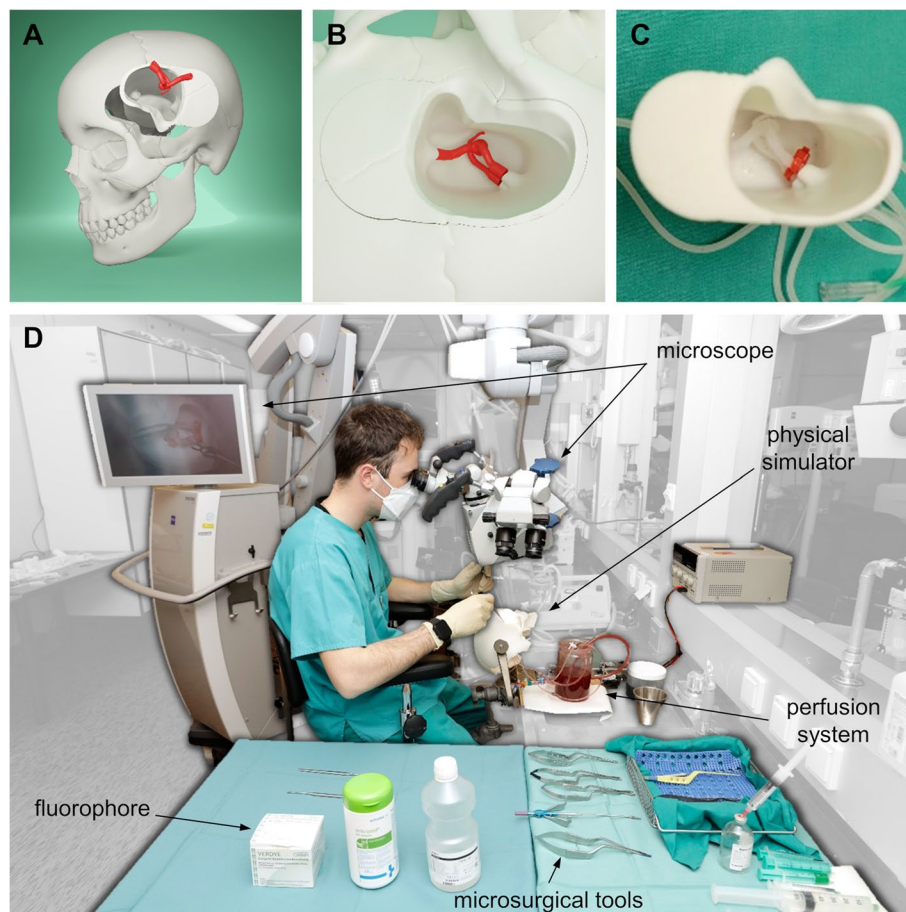


Fig. 1 Development and setup of the physical simulator. **A** Design of the generic skull with case-specific housing and case-specific aneurysm model. **B** Digital rendering of the interlocking system housing-skull, with the printed aneurysm in position in the housing. **C** Physical realization of the housing with the printed aneurysm mounted in place and connected to extension lines. **D** Full laboratory setup of physical simulator comprising surgical microscope, surgical tools (clips, clip applicators, forceps, saline solution, fluorophore for ICG-VA, syringes), physical simulator connected to voltage-controlled perfusion system

Perfusion system

A fixed perfusion system was developed by connecting a blood-coloured mimicking fluid (water and red food dye) to a voltage controlled low-power pump ($Q_{max}=1.8$ l/min when driven at 24 V) powered at an average of 3 V. The pump was then connected to a flow switch allowing rapid connection to the extension lines of each housing (Fig. 1D) and the injection of a fluorophore to simulate the diagnostic procedure of Indocyanine Green Video-Angiography (ICG-VA; VERDYE 5 mg/ml, Diagnostic Green GmbH, Germany). As the simulator was meant to simulate constructs that allow residents who never clipped an aneurysm before to gain basic experience in basic aneurysm manipulation, microscope utilization and tools familiarization, additional anatomical structures like brain parenchyma or nerves were not replicated.

Holographic simulators

Two holographic simulations implementing digital models for the AR head mounted display HoloLens1 (Microsoft, DC, USA) have been developed: a simple one without collisions between parts, and a more complex one with collisions computation. The first one involves the rendering of the aneurysms from the first four cases in the generic brain and skull, accompanied by a series of digital clip models. This facilitates a geometric comparison between the dimensions of the clips and the aneurysms, enabling a swift evaluation of various clipping strategies. However, this method does not account for model interactions or deformations. The second simulation employs computational modelling to simulate the deformation of the fifth aneurysm case in response to the application of a digitally-rendered standard bent clip. This clip is manipulated by the user through a specially designed physical tool, allowing for interactive engagement with the simulation. The physics of the aneurysm and the interaction with the clip are computed in the real-time, FEM multi-physics software SOFA Framework [46]. The aneurysm has been modelled as an elastic, isotropic biquadratic mass-spring system ($E=1$ MPa, $\nu=0.49$, vertices=301, triangles=545). Implicit Euler and conjugate gradient resolution methods were employed for solving the FEM. The system was dampened with a stiffness according to a Rayleigh damping model to simulate the presence of blood and improve solution stability. Two sets of springs were added at the geometric boundaries of the aneurysm model to simulate outpointing pressure and the presence of surrounding anatomy. The pre-selected bent-type clip has been simulated as a rotational spring system. The collision between aneurysm and clip was modelled with a penalty method tuned to have a stable resolution of the FEM during the simulation. An adaptive time step was adopted in order to achieve

real-time deformations. The simulation running on a high-end PC communicated with an application running on the AR device utilizing an internet protocol, allowing the real-time visualization of the simulated aneurysm and clip as holograms. The holographic application was developed using the Unity3D software v2021.3.4f1 (Unity Technologies, CA, USA) where the visual 3D models of the segmentations and the tools have been imported. The user manipulated the simulated, and thus holographic, clip by means of a physical tool tracked by HoloLens1 thanks to the integrated image-tracking engine Vuforia (Fig. 2A-C). A controllable on/off constraint between the clip and the applicator was implemented.

Validation of the simulators

Five specialized cerebrovascular surgeons with more than 5 years of clipping experience ($n=5$) and nine neurosurgical residents without clipping experience ($n=9$) signed consent forms and performed aneurysm clipping simulations on the physical simulator in a fully equipped neurosurgical laboratory with a surgical microscope (OPMI Pentero, Carl Zeiss Surgical GmbH) and 64 different clip types at their disposition (Fig. 1D). Each participant operated on all five manufactured cases twice, once in the morning and once in the afternoon. The sessions were supported by a technical expert who exchanged the cases and monitored the perfusion system. Every clipping simulation underwent the following: visual inspection, clip implantation attempts, ICG-VA and CT scans (standard or photon-counting). Outcomes from the ICG-VA were noted in terms of Raymond occlusion score (1: complete occlusion; 2: remnant neck; 3: incomplete occlusion). The complete collapsibility was assessed through CT scans. Subsequently, two of the five specialized surgeons ($n=2$) and an experience stratified, randomized selection of three ($n=3$) out of the nine initially included ones were exposed to the holographic simulations. Assessment of the simulators was performed through questionnaire evaluation of their content validity, face validity, construct validity, usability, usefulness and further applications (Table 1) [26, 47].

Statistical analysis

Questionnaires included Likert-like questions for the assessment of categorical variables and were administered and analysed in IBM SPSS Version 28.0 (IBM Corp., NY, USA), used also for data analysis. Descriptive statistics were employed to summarize the demographics of the study participants and the evaluated variables as frequencies and percentages. To evaluate internal consistency of the items in the questionnaire, Cronbach's Alpha (α) was computed. Values of $\alpha > 0.7$ were assumed as sufficient to ensure the items were

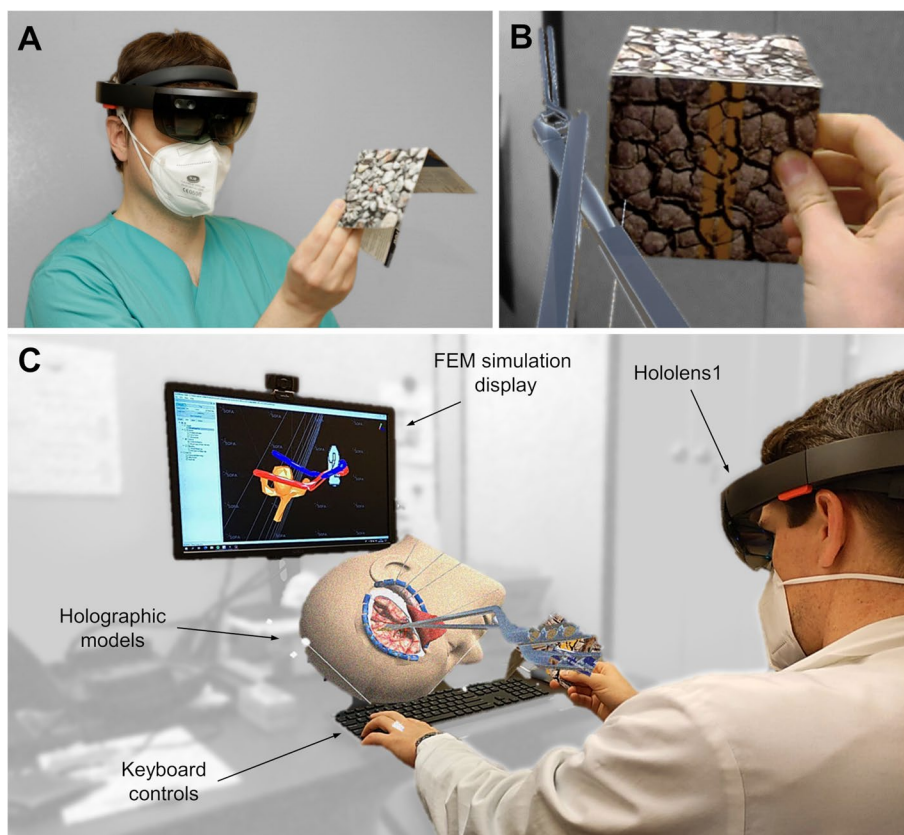


Fig. 2 Setup of the holographic simulations. **A** External visualization of the Hololens1 and physical tracker for the manipulation of the digital tools. **B** User visualization of the tracker with digital surgical tools overlaid. **C** Participant wearing Hololens1 and interacting with the FEM simulation through keyboard controls and tracker manipulation

appropriately correlated and measured the intended construct. In reporting the results, responses provided by the residents and the specialists are denoted by the symbols 'R' and 'S' respectively. To differentiate between physical and holographic simulators, the subscripts 'p' and 'h' are used.

Results

Demographics

Our study included a total of fourteen ($n = 14$) participants, 9 residents and 5 specialists. Due to a gender female-to-male ratio was 1:13, gender is not reported as it can be a potential identification of participants. Neurosurgical residents were evenly distributed in terms of training level, measured in Post-Graduate Year (PGY): 33.3% in 1–2 PGY, 33.3% in 3–4 PGY, 33.4% in 5–6 PGY. Neurosurgical specialists were all considered as highly experienced, with classification criteria having clipped at least 50 UIAs. The participants were recruited from Austria (85.72%), Denmark (7.14%) and Bulgaria (7.14%).

Physical simulator

The physical models manufactured resembled accurately the anatomical dimensions of the digital models. In particular, the assembled skull resulted in a smooth surface finishing and could be clamped firmly on a typical surgical Mayfield clamp, making the setup adjustable, ergonomic and compatible with surgical microscope and microsurgical tools (Fig. 1D). The precise geometrical dimensions eased the locking with all the housings, whose extension lines have been passed through the missing occipital bone, leading to effortless connection to the hydraulic system (Fig. 1B–D). The images of the case-specific aneurysms (Fig. 3A) have been successfully segmented and the obtained models have been prepared for silicone 3D printing (Fig. 3B). When mounted in the respective housings (Fig. 3C) and connected to the perfusion system, water tightness was confirmed, and thus their possible use under surgical microscope (Fig. 3D). The realistic wall thickness allowed to visualize the colours of the intraluminal perfused fluids (Fig. 3D, E). In this case, both the red blood-mimicking liquid and the green ICG were

Table 1 Questionnaire for the assessment of the simulators. For each question the possible answers and corresponding numerical values are reported

SIMULATORS ASSESSMENT QUESTIONNAIRE					
Content validity					
What are the best applications of the physical/holographic simulator?	Basic training				
	1	2	3	4	5
Face validity					
How do you evaluate the physical simulator dimensions for the aneurysm, the vasculature and the bone model?	Very poor	Poor	Sufficient	Good	Excellent
How do you evaluate the quality of visual realism of the physical/holographic simulator?	Very poor	Poor	Sufficient	Good	Excellent
Construct validity					
What is the quality of the physical realism of the vasculature of the physical/holographic simulator?	Very poor	Poor	Sufficient	Good	Excellent
Do you agree that the haptic sensation during clipping application of the physical/holographic simulator results in a collapse and complete occlusion of the aneurysm dome as you would expect in real case?	Strongly Disagree	Disagree	Not Agree nor Disagree	Agree	Strongly Agree
Do you agree that the average time spent on the physical simulator is realistic with respect to a real case?	Strongly Disagree	Disagree	Not Agree nor Disagree	Agree	Strongly Agree
Usability					
How do you evaluate usability and intuitiveness of the physical/holographic simulator's user interface and haptics?	Very poor	Poor	Sufficient	Good	Excellent
How do you evaluate the usability of the physical/holographic simulator?	Very poor	Poor	Sufficient	Good	Excellent
Usefulness					
How do you evaluate the usefulness of the physical/holographic simulator in understanding the patient vascular anatomy?	Very poor	Poor	Sufficient	Good	Excellent
How do you evaluate the usefulness of the physical simulator in understanding the relation of the patient's intracranial vasculature to the skull?	Very poor	Poor	Sufficient	Good	Excellent
How do you evaluate the usefulness of the physical/holographic simulator in supporting the surgeon in the decision making process of the patient positioning and approach?	Very poor	Poor	Sufficient	Good	Excellent
Do you agree that the physical simulator is useful in selecting suitable clips (comparable configurations may vary among manufacturers)?	Strongly Disagree	Disagree	Not Agree nor Disagree	Agree	Strongly Agree
Do you agree with the sentence "The physical simulator is useful in selecting valid permanent clips"?	Strongly Disagree	Disagree	Not Agree nor Disagree	Agree	Strongly Agree
Do you agree with the sentence "The physical simulator is useful in identifying non-suitable clips"?	Strongly Disagree	Disagree	Not Agree nor Disagree	Agree	Strongly Agree
Further applications					
What are the best applications of the physical/holographic simulator?	Advanced training	Preoperative planning	Intraoperative support		

visible in the visible spectrum, with the latter being visible also in the infrared spectrum and allowing to realistically replicate aneurysm reconstruction assessment (Additional file 1 and 2). The aneurysms were flushed with clear water before and after the execution of each ICG-VA, and no qualitatively appreciable fluorophore residues were observed (Fig. 3D, E). The results of dimensional accuracy through MicroCT scans are reported in Table 2. The average deviation from the original design was of 0.096 mm, ranging from 0.041 mm to 0.209 mm, while the average wall thickness was of 0.41 mm, ranging from an average of

0.39 mm to 0.44 mm (Fig. 4). A concentrated higher wall thickness can be observed in the five cases in the direction of printing, vertical with respect to the printing building plate. The results of ICG-VA as shown in Fig. 5A indicate that complete occlusion corresponding to Raymond 1 was the most frequent (68.89% of the cases), followed by Raymond 2 (17.78%) and Raymond 3 (13.33%). Despite their very thin wall, the material showed a high resistance to cyclic stresses and good tendency to collapse during clip application of a single implant: several clipping attempts have been performed on each aneurysm, twice per day over two days per

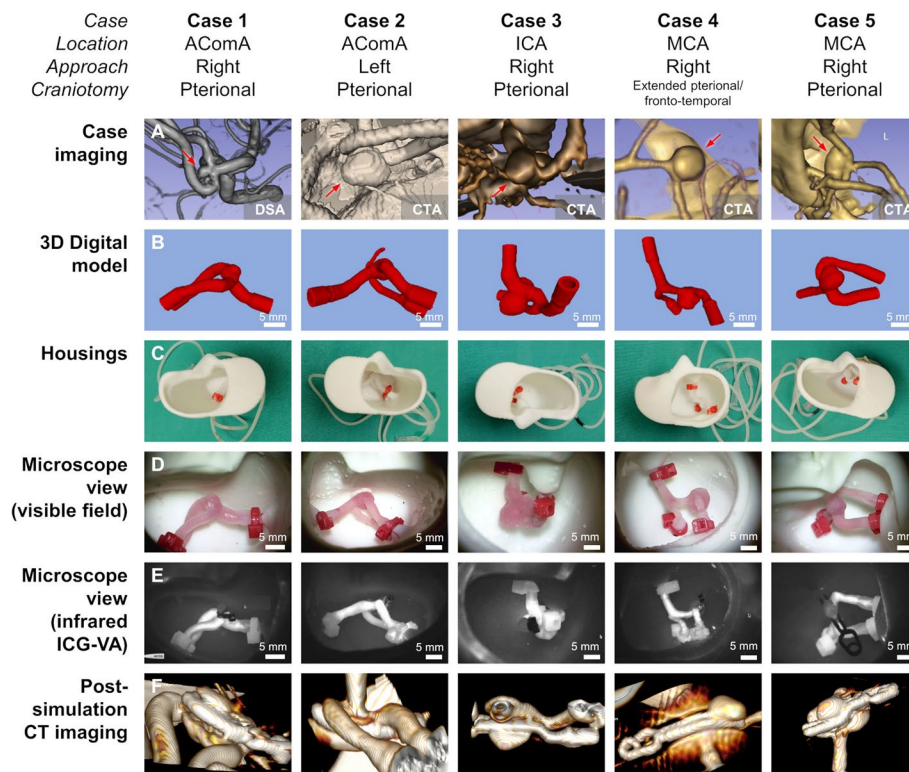


Fig. 3 Models of the selected aneurysm cases. **A** Imaging of the selected aneurysm cases. **B** 3D models for 3D printing. **C** Housings and aneurysms printed and assembled. **D** Microscope visualization of the cases perfused with blood-mimicking fluid during one of the utilization sessions. **E** Microscope infrared visualization of the cases clipped and perfused with fluorophore to perform ICG-VA. **F** CT scans of the post-simulation clipped aneurysm models in their housings

Table 2 Dimensional accuracy of the printed aneurysm cases with average deviation and sac thickness

Case number	Average deviation (mm)	Aneurysm sac thickness (mm) median (98% range)
1	0.045	0.43 (0.0741–0.6728)
2	0.127	0.39 (0.0832–0.7265)
3	0.059	0.39 (0.0853–0.6861)
4	0.209	0.41 (0.1753–9.7337)
5	0.041	0.44 (0.0937–0.7316)
Average	0.096	0.41

participant. The cumulative number of clippings performed on the models during the study was therefore more than 180, with no distinguishable mechanical difference between the aneurysm models printed and used in the study with respect to the ones not used at all. During the single training sessions, switching between housings was a short process taking less than 1 min in all cases. After the use sessions, postoperative CT scans confirmed models opacity, with sufficient contrast to

confirm complete aneurysm sac occlusion in average 73.33% of the cases and, when present, parent arteries stenosis (Figs. 3F and 5B).

Holographic simulator

In the holographic simulations, anatomical models can be visualized, rotated, and scaled using simple hand gestures, enabling a view akin to that in actual surgery (Fig. 6A). The applicator manipulation was independent from hologram scaling and intuitive to use in both simulations with and without models interaction. The simple simulation without models interaction allowed to study the relations between anatomical structures (Fig. 6B), to rapidly preselect suitable clip types and discard unsuitable clip dimensions without simulating clip opening (Fig. 6C). Complementary, in the more complex simulation the clip could be opened with keyboard controls, applied and released, resulting in a complete collapse of the aneurysm dome (Fig. 6D-F). A computation rate of the FEM simulation of 85–245 fps allowed to achieve a smooth holographic experience with visual update of

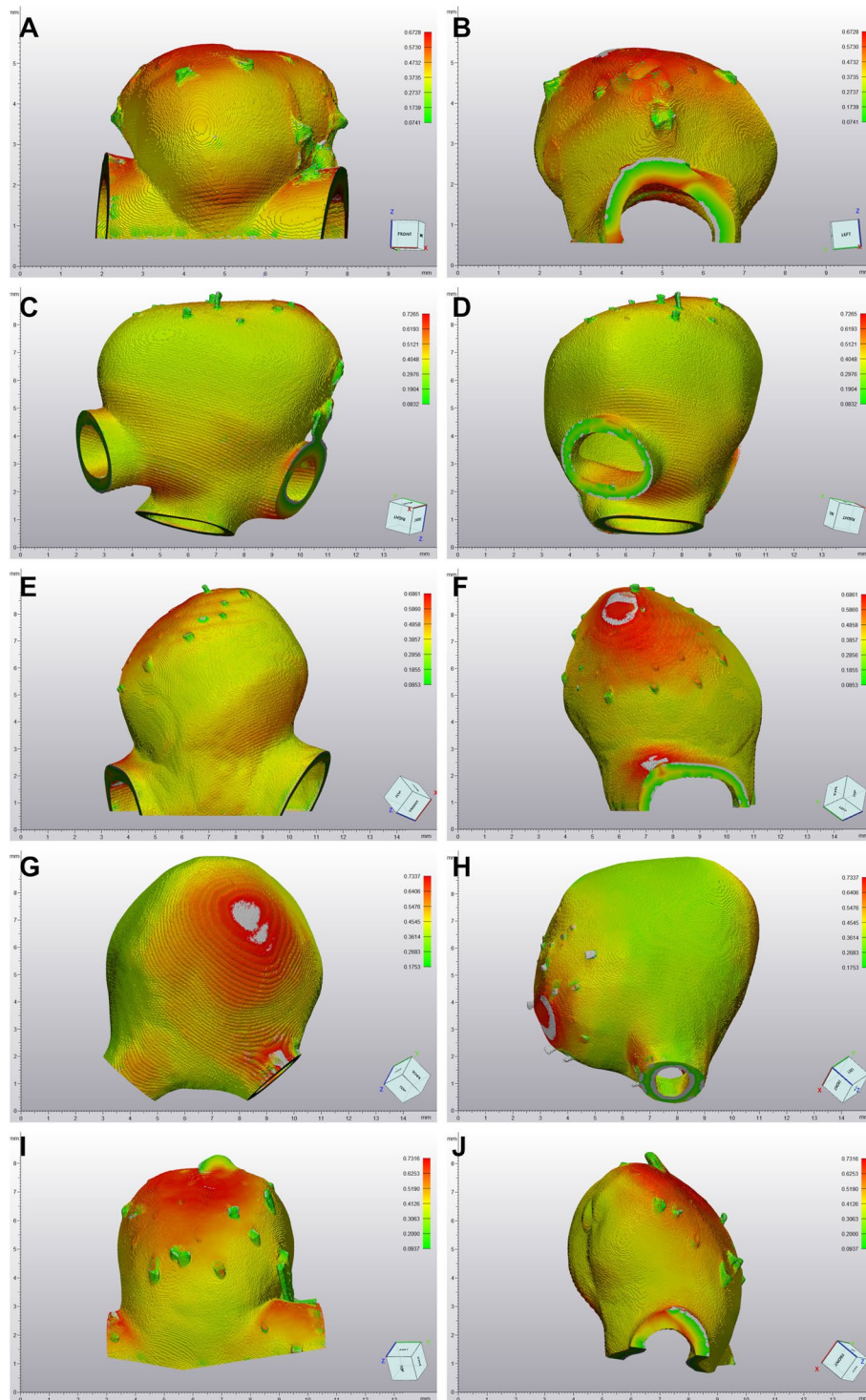


Fig. 4 Wall thickness distributions of the sacs of the printed aneurysms. The measurements of wall thicknesses are as distribution maps on aneurysm sac case 1 (A, B), case 2 (C, D), case 3 (E, F), case 4 (G, H) and case 5 (I, J)

25–50 fps without interruptions. Before and after clipping, the deactivation of the holographic, peri-aneurysmal cortical anatomy allowed unhindered inspection from any angle.

Validation

The assessment questionnaires of the physical and the holographic simulations have been completed respectively by fourteen and five participants, as reported in

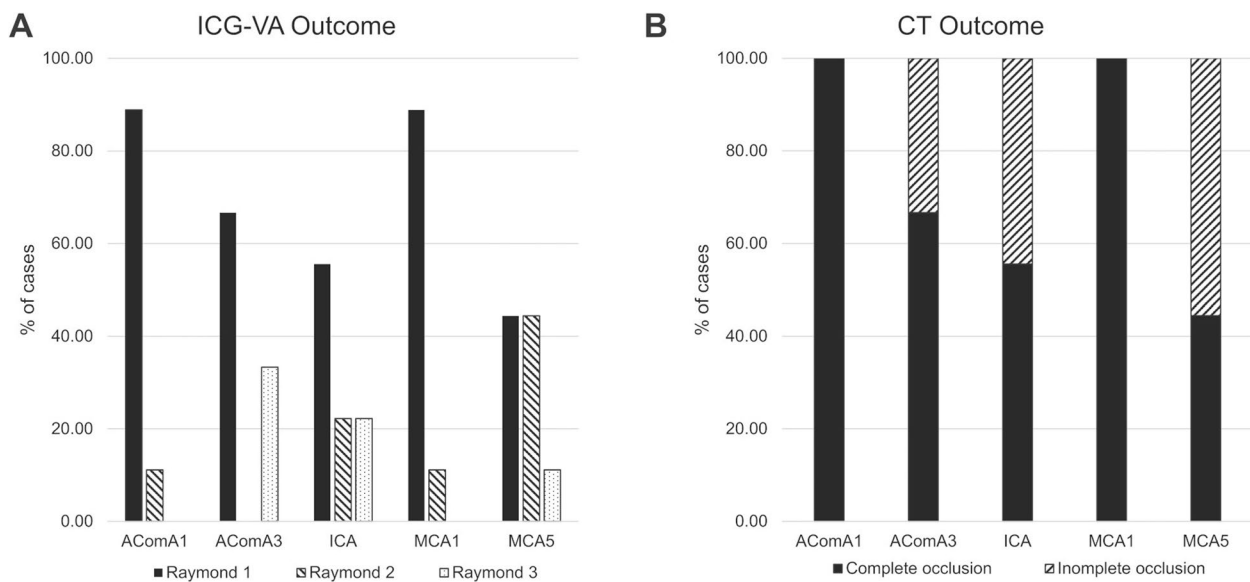


Fig. 5 ICG-VA results. Results of ICG-VA are presented in terms of Raymond occlusion score (A) and CT outcome of the assessment of total aneurysm occlusion (B)

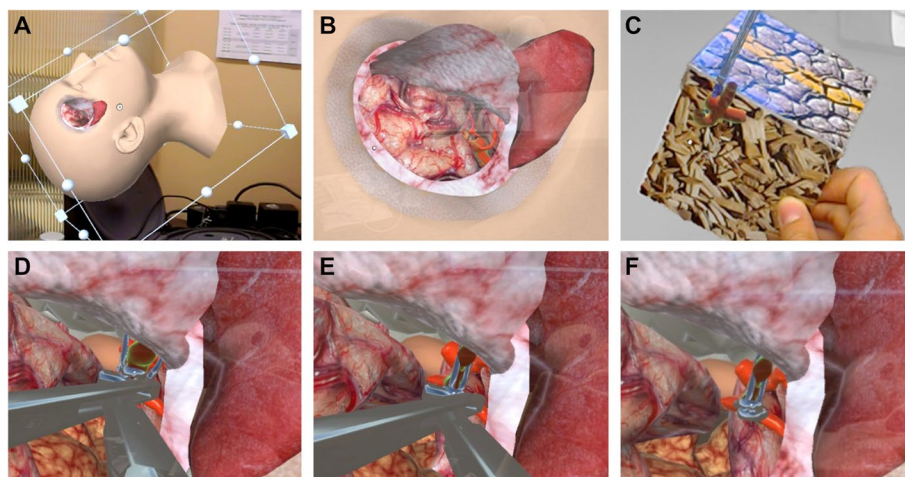


Fig. 6 Visualization of the holographic simulator from user perspective. **A** Reorientation of the anatomical models. **B** Visualization of the surgical access (case 1). **C** Comparison of clip and aneurysm dimensions without collision computation. **D-F** Holographic simulation of aneurysm clipping with clip opening, aneurysm closing and clip release

Table 3. The results confirmed the general validities of the simulators. Initially, similar content validity has been confirmed for both physical and holographic simulators, being them indicated as suitable tools for basic training by 77.78% up to 100% of the participants. Face validity of the physical simulator in terms of anatomical dimensions has been evaluated poorly ($R_p=2.89$, $S_p=2.80$), while the visual realism of both the simulators was rated as good to excellent by most of the participants ($R_p=4.22$, $S_p=4.60$, $R_h=4.67$, $S_h=4.50$). Despite the low values of answers correlation from residents, equal to $\alpha_{Rp}=0.55$, the answers

from the specialists correlated well with $\alpha_{Sp}=0.75$ and allowed to confirm face validity of the physical simulator. Due to the availability of a single set of responses, consensus alpha could not be computed for face validity of the holographic simulator. Participants evaluated positively construct validity of the physical simulator in terms of physical ($R_p=4.22$, $S_p=4.40$), haptic ($R_p=3.67$, $S_p=4.40$) and time realism ($R_p=3.00$, $S_p=4.00$). The construct validity was further supported by a high level of agreement, with $\alpha_{Rp}=0.94$ and $\alpha_{Sp}=0.87$. Conversely, evaluations of the construct validity of the holographic

Table 3 Assessment questionnaire results

SIMULATORS ASSESSMENT QUESTIONNAIRE						
Content validity						
best applications		Basic training				
	R _p	77.78				
	S _p	80.00				
	R _h	100.00				
	S _h	100.00				
		Mean	SD	Median	Min	Max
Face validity						
anatomical dimensions	R _p	2.89	0.35	0.00	2.00	3.00
	S _p	2.80	0.31	0.00	2.00	3.00
quality of visual realism	R _p	4.22	0.18	0.00	3.00	5.00
	S _p	4.60	0.25	0.00	4.00	5.00
	R _h	4.67	0.27	0.00	4.00	5.00
	S _h	4.50	0.24	0.00	4.00	5.00
Construct validity						
quality physical realism	R _p	4.22	0.18	0.00	3.00	5.00
	S _p	4.40	0.25	0.00	4.00	5.00
	R _h	3.67	0.27	0.00	3.00	4.00
	S _h	3.50	0.24	0.00	3.00	4.00
haptic sensation	R _p	3.67	0.19	0.00	2.00	5.00
	S _p	4.40	0.22	0.00	3.00	5.00
	R _h	3.00	0.40	0.00	3.00	3.00
	S _h	2.50	0.24	0.00	2.00	3.00
simulation time	R _p	3.00	0.16	0.00	2.00	4.00
	S _p	4.00	0.18	0.00	2.00	5.00
	R _h	3.00	0.40	0.00	3.00	3.00
	S _h	3.00	0.24	0.00	2.00	4.00
Usability						
usability of interface	R _p	4.56	0.25	0.00	4.00	5.00
	S _p	4.80	0.31	0.00	4.00	5.00
	R _h	3.67	0.27	0.00	3.00	4.00
	S _h	4.00	0.40	0.00	4.00	4.00
usability of simulator	R _p	4.56	0.25	0.00	4.00	5.00
	S _p	4.60	0.25	0.00	4.00	5.00
	R _h	3.33	0.27	0.00	3.00	4.00
	S _h	4.00	0.40	0.00	4.00	4.00
Usefulness						
vascular anatomy understanding	R _p	4.44	0.22	0.00	3.00	5.00
	S _p	4.60	0.25	0.00	4.00	5.00
	R _h	4.67	0.27	0.00	4.00	5.00
	S _h	4.50	0.24	0.00	4.00	5.00
vasculature - skull relation	R _p	4.22	0.18	0.00	3.00	5.00
	S _p	4.60	0.25	0.00	4.00	5.00
patient positioning and approach	R _p	4.67	0.27	0.00	4.00	5.00
	S _p	4.20	0.18	0.00	3.00	5.00
	R _h	4.00	0.16	0.00	3.00	5.00
	S _h	4.00	0.40	0.00	4.00	4.00

Table 3 (continued)

SIMULATORS ASSESSMENT QUESTIONNAIRE							
suitable clips selection	R_p	4.78	0.30	0.00	4.00	5.00	
	S_p	5.00	0.40	0.00	5.00	5.00	
	R_h	4.00	0.16	0.00	3.00	5.00	
	S_h	5.00	0.40	0.00	5.00	5.00	
permanent clips selection	R_p	4.56	0.25	0.00	4.00	5.00	
	S_p	4.80	0.31	0.00	4.00	5.00	
	R_h	4.33	0.27	0.00	4.00	5.00	
	S_h	4.50	0.24	0.00	4.00	5.00	
non-suitable clips selection	R_p	4.44	0.25	0.00	4.00	5.00	
	S_p	4.60	0.25	0.00	4.00	5.00	
	R_h	4.33	0.27	0.00	4.00	5.00	
	S_h	4.50	0.24	0.00	4.00	5.00	
Further applications							
best applications			Advanced training	Preoperative planning	Intraoperative support		
	R_p	77.78		88.89	11.11		
	S_p	80.00		80.00	0.00		
	R_h	33.33		66.67	0.00		
	S_h	0.00		50.00	0.00		

P physical simulator, h holographic simulators, R residents, S specialists

simulator revealed lower scores for physical realism ($R_h=3.67$, $S_h=3.50$), haptic realism ($R_h=3.00$, $S_h=2.50$) and operational time ($R_h=3.00$, $S_h=3.00$). Agreement on construct validity was mixed, as α_{Rh} could not be calculated due to the availability of a single set of responses, while it was calculated $\alpha_{Sh}=0.94$. Regarding usability, both simulators were rated highly for their interfaces ($R_p=4.56$, $S_p=4.80$, $R_h=3.67$, $S_h=4.00$) and overall usability ($R_p=4.56$, $S_p=4.60$, $R_h=3.33$, $S_h=4.00$). Strong consensus was confirmed with $\alpha_{Rp}=1$, $\alpha_{Sp}=0.75$ and $\alpha_{Rh}=0.94$. The alpha value α_{Sh} could not be calculated, similar to the previous scenario. Several items were dedicated to usefulness assessment, that has been highly rated for both the simulators. In particular, the highest scores have been observed in clip selection usefulness, for which values of $R_p=4.78$ and $S_p=5.00$ have been obtained for suitable clip selection, values of $R_p=4.56$, $S_p=4.80$ for permanent clip selection and values of $R_p=4.44$, $S_p=4.60$ for non-suitable clip selection. Similar results have been observed for the holographic simulator, presenting values of $R_h=4.00$, $S_h=5.00$ for suitable clip selection, $R_h=4.33$, $S_h=4.50$ for permanent clip selection and $R_h=4.33$, $S_h=4.50$ for non-suitable clip selection. Values of $\alpha_{Rp}=0.94$, $\alpha_{Sp}=0.9$, $\alpha_{Rh}=0.95$ and $\alpha_{Sh}=0.83$ confirmed agreement regarding confirming the usefulness of both the simulators. The possible further applications of the simulators were indicated mainly as preoperative planning with $R_p=88.89\%$, $S_p=80\%$ for the physical, and $R_h=66.67\%$, $S_h=50\%$ for the

holographic simulator. Advanced training was reported mainly for the physical simulator with $R_p=77.78\%$, $S_p=80\%$, and intraoperative support was reported only by few residents with $R_p=11.1\%$.

Results of the study including 14 participants confirmed the comprehensive validity of the simulators. The physical simulator accurately replicated the sub-millimetric patient-specific anatomy, along with the holographic simulators. Both types demonstrated mechanical and dimensional accuracy and proved their validity in terms of face, content, and construct, as well as usability and usefulness. Notably, they resulted useful in selecting suitable and non-suitable clips, with potential applications in preoperative planning.

Discussion

Surgical training is currently in need for solutions that can enhance patient safety, improve effectiveness, and increase accessibility, especially in front of limited microsurgical exposure and the increasing complexity of the microsurgically treated UIAs, consequence of the rise in the portion of endovascular treated UIAs [48]. To be integrated into surgical training curricula, simulators need to be effective and validated. Training technologies should satisfy those requirements and feature case-specific, highly realistic anatomy in high volumes in order to represent valuable alternatives to animal or cadaver training. This way, simulators can not only expose the trainees to

best practices, but also provide safe environments to train adverse events management, thus accelerating residents' learning curve, increase confidence and improve patient safety [6]. The development of simulations encourages the adoption of new technologies, yet often introduces challenges such as high costs, complex familiarization processes, and the need for technical support, which can diminish their cost-effectiveness. Therefore, low costs and plug-and-play capabilities should be prioritized in the design of training simulations. We identified AM and AR as complementary technologies providing the first the flexibility of rapidly manufacturing complex anatomies, and the second the visual realism of digital models. We utilized a high-resolution silicone 3D printing technology for the realization of the physical simulation, enabling the production of case-specific intracranial vessel replicas at low manufacturing costs. The results of dimensional analysis reveal an average dimensional deviation in the order of the wall thickness of the models that, in light of the good dimensional accuracy of wall thickness, is interpretable as a consequence of the light deformation of the model when introduced in the MicroCT scanner. Despite the phantoms could realistically collapse thanks to the reduced wall thickness, they did not show any residual deformation after repeated use. The overall concordance between the outcomes of ICG-VA and CT indicates that ICG-VA simulations could serve as an effective evaluation tool, even when CT is not available. The observed discrepancies between the two sets of results may be attributed to the fact that aneurysms assessed with a Raymond score of 1 or 2 can appear as completely occluded in CT scans. General validity of the physical simulator was confirmed. Despite the absence of other anatomical structures apart from the UIA, the level of complexity of the physical simulator was sufficient to ensure content, face and construct validity, but not so high to hinder user experience in terms of usability and intuitiveness. In particular, the properties of physical realism and haptic realism were strongly confirmed, as well as usability. This derived probably by the compatibility of the simulator with a laboratory completely resembling an operational room in terms of positioning possibilities, tools, microscope and procedure steps. In this scenario, intuitiveness was observed by a natural behaviour of the specialists approaching the simulator, preparing the set before being explained the step by step use of the simulator. Remarkably, the simulator was indicated as highly useful for the specific procedure of UIA clipping in selecting possible, permanent and non-suitable clips. This could explain the reason why the most suitable further application of the physical simulator is preoperative planning, in which the main challenges of clip selection and patient positioning can be well tackled with this simulator. Conversely, the

holographic simulators bring the complementary benefits of digital solutions. In details, the first and simpler holographic simulator allows to rapidly compare clip dimensions with aneurysm sac, based on the assumption that sac dimensions remain almost unchanged upon collapse. Differently, the FEM simulation relies on the opposite assumption, making the computation of deformations needed to accurately simulate the aneurysm sac. The advanced visualization functionalities available in the holographic simulation allow to achieve a higher realism without the complexities of the physical case, with the unique possibility of enlarging, activating or hiding the digital models. The interactive clipping simulation represents the first integration of FEM with AR head-mounted devices. Content validity was confirmed also for the holographic simulator, for which face validity scored extremely high thanks to the additional anatomies and realistic textures used. The poor scores of construct validity can be motivated with the absence of a haptic feedback, that does not allow to physically perceive the physical realism, leading to mainly "not agree nor disagree" answers. The good scores of usability reflected the short learning curve of the users, that rapidly familiarized with the AR environment and the holographic simulations. The possibility of deepening the visualization and deactivating the models can explain the high scores of usefulness in understanding vascular anatomy. This allows to proficiently study aneurysm morphology and to preselect plausible clips without manufacturing costs and discards. This can also suggest higher utility of the simpler holographic simulation to understand the anatomy and study the general clipping approach, and higher utility of the interactable simulation for clip selection.

This work presents some potential limitations. During the development of the physical simulator we encountered the same manufacturing challenges described in literature, starting with aneurysm sac wall thickness: it could not be derived by available images, so a constant wall thickness equal to 0.4 mm was assumed, representing the first deviation from morphological reality. Additionally, the models were printed without correction of the intraluminal pressure of when the images were acquired, leading to an over-pressurized model. Nevertheless, the effect of additional pressure on the models when perfused was limited to a minimal inflation. Constant perfusion did represent another deviation from reality. The adoption of pre-stress correction, together with a pulsatile fluid pump, can overcome these limitations. The absence of brain parenchyma in the physical simulator could explain the lower score of anatomical dimensions of the physical simulator. Moreover, due to the absence of arachnoid to dissect to access the aneurysm and its surrounding, simulation time was sensibly

shorter and specialists' scores about approach study usefulness were average. Despite the absence of simulated brain, the physical simulation replicates the complexities of UIA clipping for residents training and allowed to confirm construct validity. The perceived fragility of the vessel, despite its stress resistance demonstrated throughout the entire study, represented the main challenge for the trainees, purposed to learn principles like respect for tissue, instrument handling, knowledge of instruments and specific procedure [49]. The implementation of mechanically and visually realistic case-specific brain phantom could overcome these limitations and allow the simulator to be used also for advanced training, including in future steps also arachnoid dissection and dura opening. Intraoperative support was not reported as possible application probably because of sterilization processes limiting its use in the operational field. The low realism of simulation time represented a limitation also for the holographic simulations, that together with the absence of haptic feedback did not allow to confirm construct validity. Even though AR simulations could benefit by the addition of haptic feedback manipulators, their use tailored for anatomy understanding and (possibly) preoperative planning do not make it a requirement. The use of the HoloLens 1 system still represented the main limitation, affecting usability and not allowing the use of both hands for the manipulation of tools in the holographic simulations. This is not expected to remain an issue once the latest generation (HoloLens 2) is implemented instead [50]. Preoperative planning was indicated as the most suitable further application of the simulators after basic training. If, on the one hand, the brain parenchyma brings a higher visual realism, improve face validity and limit the available space for clips, on the other hand it was proven through the holographic simulators that it is not strictly necessary to use the simulators in preoperative planning and do clips selection. The integration of 3D printing and AR based simulators is envisioned by the authors. Such simulations can bring the potential of providing a comprehensive platform to train microsurgical skills. Furthermore, with the increase of available simulators, the need for a unique and reproducible evaluation measurement scale is emerging, which shall be developed and tested in a controlled environment.

Conclusions

The need for case-specific, microsurgical training tools is growing and unmet. In this work, low-cost physical and digital simulators with state-of-the-art realism have been developed and validated. Furthermore, their usefulness and future applications have been evaluated.

Abbreviations

UIA	Unruptured Intracranial Aneurysm
AC	Aneurysm Clipping
EVT	Endovascular Techniques
AM	Additive Manufacturing
AR	Augmented Reality
VR	Virtual Reality
FEM	Finite Element Modelling
AComA	Anterior Communicating Artery
ICA	Internal Carotid Artery
MCA	Middle Cerebral Artery
DSA	Digital Subtraction Angiography
CT	Computer Tomography
MRI	Magnetic Resonance Images
ICG-VA	Indocyanine Green-video angiography
PGY	Post-Graduate Year

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s41205-024-00235-w>.

Video 1: ICG-VA simulation on physical simulator with Raymond 1.

Video 2: ICG-VA simulation on physical simulator with Raymond 3.

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Authors' contributions

(I) Concept and design: C.L., D.P., M.F., P.M.C., R.C.L.A.; (II) Collection and assembly of data: C.L., D.P.; (III) Data analysis and interpretation: C.L., D.P., M.F., R.C.L.A.; (IV) Final approval of manuscript: All authors.

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Availability of data and materials

The experimental data and the simulation results supporting the conclusions of this article are included within the article and its additional files.

Declarations

Ethics approval and consent to participate

This research study was approved by the institutional ethical commission of Medical University of Vienna (Nr. 1593/2021).

Consent for publication

Not applicable.

Competing interests

The authors applied for patent protection of part of the methods described in this manuscript, and its potential commercialization is being considered by the authors.

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