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**Simulation Training in Neurosurgery:
Development and Evaluation of a Practical Training Simulator
for the Microsurgical Management of Middle Cerebral Artery Aneurysms**

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Abstract:

Neurosurgery demands significant expertise and technical skills, traditionally acquired through training in operative settings. The introduction of alternative treatment options as well as socio-economic changes over the past two decades, however, have led to a significant decline in surgical caseload, limiting training opportunities for young neurosurgeons to develop and refine their skills. This shift is perhaps nowhere more impactful than in the field of vascular neurosurgery, where the emergence of endovascular treatment options has led to a continuous decline in microsurgically managed aneurysm cases. Despite this trend, the surgical management often remains the superior treatment method, particularly in middle cerebral artery aneurysms, underscoring the importance of training opportunities to maintain surgical expertise. Synthetic simulators have the potential for targeted, hands-on training in a controlled environment. Yet, the incorporation of such simulators into the neurosurgical curriculum remains a challenge due to their lack of realism, limited usability and high acquisition costs. This work aims to address these challenges by developing a novel practical, cost-effective, easily reproducible yet highly realistic simulator for the microneurosurgical clipping of middle cerebral artery aneurysms employing additive manufacturing, rheological analyses, and neurosurgical expertise. Tested by 12 participants across different neurosurgery experience levels, the simulator demonstrated high face and content validities across all categories, derived from a 5-Point Likert scale with a mean score of 4,9/5. Objective assessments of surgical performances revealed that the simulator accurately reflects the skills of the participants, signaling a high construct validity. The efficacy of the simulator was showcased by a rapid and significant acceleration in surgical precision and quality, particularly among novice medical students and neurosurgical residents.

Key words: Simulation Training; Surgical Simulator; Face, Content and Construct Validity; Neurosurgical Education; Aneurysm; Clipping, Rheology

Contents

1. Introduction.....	5
2. Materials and methods.....	10
2.1 Data acquisition	10
2.2 Construction of the model	11
2.2.1 Construction of the skull.....	13
2.2.1.1 Digital reconstruction and post-processing of the skull	13
2.2.1.2 Additive manufacturing of the skull.....	15
2.2.1.3 Skull model: reusable parts.....	16
2.2.1.4 Skull model: replaceable parts.....	18
2.2.2 Construction of the Sylvian fissure	19
2.2.2.1 Segmentation and digital post-processing of the brain.....	19
2.2.2.2 Additive manufacturing of the Sylvian fissure model.....	20
2.2.2.3 Substudy on simulating the living brain	22
2.2.2.4 Casting of the Sylvian fissure.....	28
2.2.3 Construction of cerebral arteries and aneurysms.....	30
2.2.3.1 Segmentation and digital post-processing of the Circulus arteriosus Willisii.....	30
2.2.3.2 Additive manufacturing of the Circulus arteriosus Willisii	30
2.2.3.3 Modeling of the Circulus arteriosus Willisii	32
2.2.3.4 Modeling of MCA bi-/trifurcation aneurysms.....	33
2.2.4 Construction of the meninges	35
2.2.4.1 Mimicking the arachnoid membrane.....	35
2.2.4.2 Mimicking the dura mater	37
2.2.5 Simulator assembly	38
2.3 Study design	39
2.3.1 Study participants.....	39
2.3.2 Simulation setup	39
2.3.3 Simulation process	40
2.3.4 Quality assessment	43
2.3.5 Statistical analysis	47
3. Results.....	48
3.1 Efficacy of simulation	48
3.1.1 Face and content validity	48
3.1.2 Construct validity.....	50
3.2 Cost analysis	53
4. Discussion.....	54
4.1 Interpretation.....	54
4.2 Limitations	58
4.3 Conclusion	58
5. Summary (German)	60
6. Figures.....	61
7. Tables.....	64
8. References.....	65
9. Danksagung	72
10. Ehrenerklärung.....	73
11. Darstellung des Bildungsweges	74

Abbreviations

ACA	Anterior Cerebral Artery
AcoA	Anterior Communicating Artery
BRAT	Barrow Ruptured Aneurysm Trial
°C	Celsius
CAD	Computer-aided Design
CAW	Circulus Arteriosus Willisii
CT	Computed Tomography
CTA	Computed Tomography Angiography
CTI	Centro de Tecnologia da Informação Renato Archer
CSF	Cerebrospinal Fluid
DICOM	Digital Imaging and Communications in Medicine
DSA	Digital Subtraction Angiography
EVD	External Ventricular Drain
EANS	European Association of Neurosurgical Societies
GCS	Glasgow Coma Scale
H&H	Hunt and Hess
ICA	Internal Cerebral Artery
ICP	Intracranial Pressure
ISAT	International Subarachnoid Aneurysm Trial
ISUIA	International Study of Unruptured Intracranial Aneurysms
kPa	Kilopascal
MCA	Middle Cerebral Artery
MCAAT	Middle Cerebral Artery Aneurysm Trial
MRA	Magnetic Resonance Angiography
MRI	Magnetic Resonance Imaging
N	Newton
OSAACS	Objective Structured Assessment of Aneurysm Clipping Skills
OSATS	Objective Structured Assessment of Technical Skills
PAM	Pascal
Pa	Polyacrylamide
PLA	Polyactide acid
PVA	Polyvenylalcohol
PETG	Polyethylene Terephthalate Glycol
SAH	Subarachnoid Hemorrhage
RCT	Randomized Control Trial
SAC	Stent-Assisted Coiling
SF	Sylvian Fissure
STL	Stereolithography
TOF	Time of Flight
UIA	Unruptured Intracranial Aneurysms
Vs.	Versus
WTD	Work Time Directive
3D	Three-dimensional

1. Introduction

Neurosurgery deals with the treatment of complex diseases of the central and peripheral nervous systems. As a highly specialized medical profession, neurosurgery requires considerable expertise and a high level of technical skills that can only be acquired through practice and repetition, commonly referred to as the caseload. The predominant model for neurosurgical education is grounded on the "graduated responsibility training" system, a concept introduced in the early 20th century by the surgeon William Stewart Halsted.¹ Halsted, an American surgeon and pioneer of one of the earliest surgical training programs at Johns Hopkins University in Baltimore, crafted a residency model inspired by surgical training practices he had previously observed in Germany.² The strict pyramidal structured residency program that he implemented was based on gained experience through intense and repetitive opportunities, commonly referred to as the surgical caseload, and exemplified by the "see one, do one, teach one" approach.

With current training methods still largely consisting of observing and assisting in surgery, the conditions necessary to maintain a structured gradual training program have dramatically shifted over the past decades with a severe impact on the quality of surgical skill acquisition and maintenance. The resulting impact is particularly noticeable in the field of neurosurgery, which is considered as one of the most liable fields in medicine with the majority of a neurosurgical errors being considered technical in nature and as such preventable.^{3,4}

A breaking point for the neurosurgical education in Europe was the enactment of the *Work Time Directive* (WTD) by the European Union in 2003, which instituted a resident work-hours restriction. The results of a survey distributed among the European Association of Neurosurgical Societies (EANS) member countries in 2018 revealed a decline of nearly 30% of the mean total number of surgical procedures performed by neurosurgical residents throughout residency following the implementation of the WTD.⁵⁻⁷ While the minimum safety and health requirements for the organisation of working time, as introduced by the WTD, were a major step towards improving health and safety at work, it severely lowered the surgical caseload available for trainees to develop and hone surgical skills.

Another key factor contributing to the reduction in surgically managed cases is the advent of alternative therapeutic modalities following the rapid advancements in medicine and technology particularly over the past two decades. The resulting impact is perhaps nowhere greater than in the field of vascular neurosurgery, where the microsurgical management of cerebral aneurysm via clipping, first introduced in 1938 by Walter Dandy, has remained the gold standard.^{8,9} This approach, which was first performed under a microscope by Kurze in 1957¹⁰, was later championed by Mahmut Gazi Yaşargil who underscored the importance of the microscope in performing atraumatic

intracranial procedures. His methods allowed surgeons to safely navigate the subarachnoid space, expanding their operative field, making complex procedures more manageable and less invasive.^{11 12,13} With the development of endovascular techniques to visualize cerebral vessels by the Portuguese neurologist Egas Moniz in 1955¹⁴, and the introduction of detachable balloons in 1974, the era of endovascular neurosurgery was ushered in with treatment of the first patient with cerebral aneurysm using detachable coils by Guglielmi in 1990.¹⁵

A paradigm shift in the treatment of cerebral aneurysm was caused by the 2002 published multicenter randomized control trial (RCT) conducted by the International Subarachnoid Aneurysm Trial (ISAT)¹⁶ group, which compared the safety and efficacy of endovascular coiling versus surgical clipping for the treatment of ruptured cerebral aneurysms. Early results of ISAT, at 1-year follow-up, suggested the superiority of endovascular management via detachable platinum coils compared to microneurosurgical clipping regarding ease of access and outcome with a reduced relative risk of dependence or death by 22.6%, particularly in patients older than 50 years of age and / or aneurysm located at the posterior circulation. These results were reinforced by the 2003 published International Study of Unruptured Intracranial Aneurysms (ISUIA)¹⁷, in which unruptured aneurysms were randomized to coiling versus clipping or observation, showing a 22% relative risk reduction of endovascular approach over conventional surgery.

Following these studies, the method of choice for treating intracranial aneurysms rapidly shifted in favor of endovascular embolization with 56.6% of ruptured and almost two-thirds (65.6%) of unruptured aneurysms today being treated endovascularly.¹⁸

The initial results of ISAT and ISUIA were put into perspective by the long-term results of ISAT as well as those of the Barrow Ruptured Aneurysm Trial (BRAT), a 2012 study comparing the safety and efficacy of microsurgical clip occlusion and endovascular coil embolization for the treatment of acutely ruptured cerebral aneurysms. The results of BRAT indicated that although initial morbidity may be lower with endovascular treatment, the microsurgical management of cerebral aneurysms via clipping continues to offer the most robust long-term treatment option with a lesser risk of aneurysm recurrence, rerupture, and need for retreatment.¹⁶⁻¹⁸

This is particularly true in the management of middle cerebral artery aneurysms where surgical clipping has shown to be superior in providing better short- and long-term occlusion rates while matching coiling in terms of clinical outcome.²²⁻²⁸ These findings were further corroborated by the 2022 published data from the Middle Cerebral Artery Aneurysm Trial (MCAAT)^{29,30}, a multicenter, prospective, randomized controlled clinical trial comparing surgical clipping and endovascular treatment 291 patients with unruptured intracranial aneurysms (UIAs), highlighting the benefit of microsurgical clipping over endovascular treatment options in terms of the frequency of the primary

outcome of treatment failure. And considering the growing detection of UIAs due to better healthcare coverage, screenings and improvements in imaging quality and software³¹⁻³³, the microneurosurgical treatment of cerebral aneurysms remains a crucial skill that every cerebrovascular surgeon should acquire and hone early on in their career.

Confronted with the challenge to train the next generation of vascular neurosurgeons despite a decline in surgical caseload, patient-safety concerns and work-hour regulations, there has been an increased demand for alternative, efficient, and safe surgical training methods, that allow deliberate practice of neurosurgical procedures.

Cadaveric training, as the oldest form of simulation, poses several limitations as a surgical training tool: access to cadavers is narrowed by limited availability, high preparation costs, and the need for a full laboratory with biohazard precautions. Their efficacy is limited by the absence of task-specific pathologies and limited reusability.³⁴ Their realism is limited by differences in the mechanical and tactile properties of cadaveric brain tissue compared to the living brain^{35,36}, as encountered during surgery, which are most likely caused by preservation techniques and long-term absence of cerebral perfusion.³⁷

Recent technological developments have opened new paths in neurosurgical simulations, particularly software-based simulations based virtual- or augmented reality technologies.³⁸⁻⁴¹

Virtual simulations allow a unique visualization of intraoperative anatomy. Their main advantage is the ability to undo and repeat steps without destroying physical models. For aneurysm clipping, craniotomy and surgical approaches can be trained with patient-specific imaging data. A virtual clip can be applied to the aneurysm and the success of clipping can then be rated by simulation of the blood flow before and after clipping. Virtual reality systems allow the user to fully immerse into the environment of an operating room with all equipment included, leading to an even more realistic experience.⁴²⁻⁴⁶

However, the biggest limitation to virtual simulations remains the lack of haptic feedback and the absence of microneurosurgical instruments. Although some existing models work with haptic input devices and can be connected to instruments like clipping forceps to allow real-time force feedback^{47,48}, virtual models cannot offer a hands-on experience comparable to real-life surgery, which severely limits the transferability of learned skills into real-life settings.

With cadaveric and screen-based simulations being limited as surgical training tools, the market for haptic neurosurgical training simulators has seen considerable growth in recent years, supported by advancements in 3D printing technology. Synthetic simulators have the potential to provide a realistic, hands-on experience and improve dexterity and spatial awareness skill that can be directly transferred into a real surgical setting.

Yet, despite the majority of program directors and residents wishing for more extensive usage of simulators in neurosurgical training ⁴⁹, most of the currently available haptic simulators lack basic visual, tactile and anatomical properties relevant for the acquisition and improvement of technical skills and therefore do not meet the basic requirements necessary to be used as effective training tools as they.⁵⁰⁻⁵²

The aim of this work is the development and assessment of an effective training simulator for the microsurgical management of MCA aneurysms. The preliminary understanding of the intracranial anatomy, allowing the correct head positioning, spatial awareness, orientation, and navigation under the microscope, the microneurosurgical dissection of the Sylvian fissure, and exploration of the subarachnoid cisterns, are crucial steps in the microsurgical management of middle cerebral artery aneurysms,⁵³⁻⁵⁶ which a clipping simulator must contain to be used as an effective training tool. As the fundamental premise of simulation training is that skills acquired in simulated settings should be transferable to real-life scenarios, it is essential to subject the simulator to rigorous evaluation to establish its validity defined as the quality of being true, accurate, and aligned with reality.⁵⁷

For this purpose, the following prerequisites were defined for the construction, evaluation and usage of the simulator as a practical training tool:

- **Face validity:** The simulator must accurately portray relevant anatomical structures, landmarks, and pathologies and reflect the tactile properties of the skull, cerebral meninges, brain tissue, and vascular structures as encountered in vivo.
- **Content validity:** The simulator must contain all relevant anatomical structures necessary to simulate the crucial steps of the procedure and allow for variations in surgical strategy.
- **Construct validity:** The simulator must be able to differentiate users' surgical abilities.
- **Efficacy:** Training with the simulator should improve technical skills.
- **Accessibility:** The simulator must be reproducible without extensive investments or technical expertise to allow skill acquisition through repetition and experience.

The initial phases of this validation process involve assessing face and content validity, both of which rely on expert judgment. Face validity is attained when experts collectively agree that the simulator effectively teaches or assesses what it aims to. Content validity, also grounded in expert opinion, evaluates whether the simulator encompasses the requisite steps and skills of a procedure. Construct validity is ascertained by examining the simulator's capability to discern varying levels of surgical proficiency.

In order to ensure that these requirements are met, this thesis will also encompass a critical substudy. This substudy aims to identify the optimal substitute for living brain tissue, a crucial element in achieving both visual and tactile realism. The selection of this substitute is paramount, as it directly influences the simulator's ability to mimic the intricate properties of brain tissue experienced during actual neurosurgical procedures.

To comprehensively evaluate the simulator's educational utility, practicability, and efficacy, this work includes extensive subjective and objective assessments. These evaluations will be conducted by individuals at various stages of their neurosurgical career: novice students, residents, and experienced neurosurgeons. Through their feedback and performance metrics, this study seeks to establish the simulator's effectiveness in enhancing technical skills, boosting confidence in the operating room, and ensuring that the skills acquired are transferable to real-life surgical settings.

Finally, as this work aims to facilitate skill acquisition through repetition and experience, ensuring accessibility and cost-effective reproducibility of the simulator will be a crucial prerequisite for implementing the model as a valuable tool in the repertoire of neurosurgical training.

2. Materials and methods

2.1 Data acquisition

With the approval of the local ethics committee of the Otto-von-Guericke University Magdeburg, (ethics vote number: RENOVA 94/20) imaging datasets (computed tomography angiography [CTA], and magnetic resonance imaging [MRI]) of a 52 year old male with an incidental basilar tip aneurysm who underwent endovascular treatment in our hospital, were used for thresholding-based segmentation and reconstruction of the skull, brain and the Circulus arteriosus Willisii (CAW).

The selection of this patient's imaging data for the construction of the model was based on following factors:

- The patient had received a high-resolution CTA imaging of the skull, which served as basis for the digital reconstruction of the skull, including the eye cavities, facial bones, and paranasal sinuses. Furthermore, the patient's skull was intact as he had not undergone any neurosurgical treatment.
- The patient had received an MRI of the brain including a high-resolution contrast enhanced T1-weighted sequence with a slice thickness of 0.75 mm, which served as basis for the digital reconstruction of the brain as well as the CAW and connected vessels.
- The patient had no intracranial masses or intraparenchymal lesions or defects deforming the brain or ventricles.

2.2 Construction of the model

The construction of the simulator based the patient’s imaging data was executed in four key stages as presented in **Figure 1**.

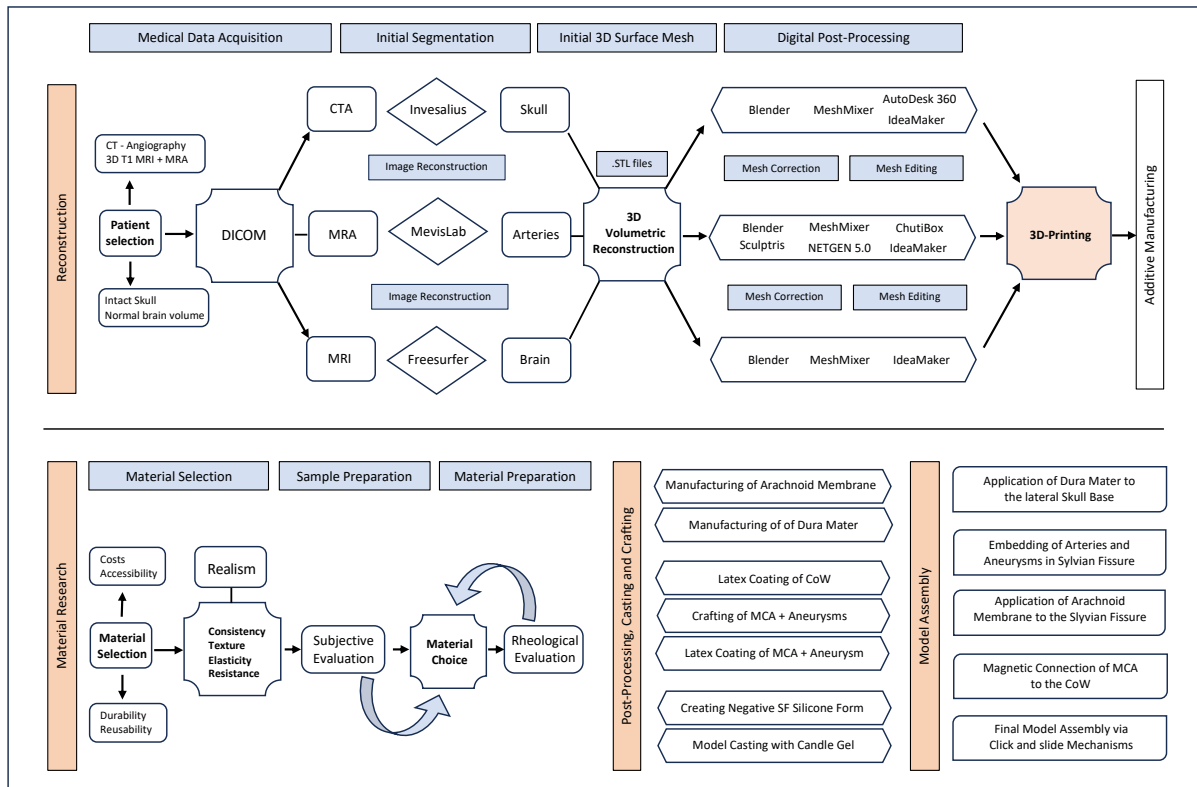


Figure 1: Structured workflow detailing the reconstruction, digital editing, additive manufacturing, material research, and crafting process of the model.

I: Digital reconstruction: This initial phase involves the meticulous segmentation, reconstruction and of the human skull, brain, and vascular structures with high fidelity, ensuring anatomical accuracy. The reconstructed models are then digitally post-processed and edited for further refinement and preparation for the manufacturing process. The segmentation, reconstruction, and digital post-processing of the model in all its parts were exclusively executed with freely available 3D (three-dimensional) reconstruction, slicing, and editing software as listed in **Table 1**.

Table 1: List of software programs used for segmentation, reconstruction, and digital post-processing of the model.

Software	Version	Developer	Main Features
InVesalius	3.1.1	CTI Renato Archer	3D reconstruction from CT and MRI, STL export
FreeSurfer	7.3.0	Martinos Center for Biomedical Imaging	Pial surface segmentation
Blender	3.4.1	Blender Foundation	3D modeling, animation, simulation, rendering
Meshmixer	3.5.474	Autodesk Inc.	3D mesh editing, repair, and sculpting
IdeaMaker	5.0.3	Raise3D Technologies, Inc.	3D printing slicing software
Chitubox	1.9.0	CBD-Tech	Slicing software for resin 3D printers
MeVisLab	3.4.0	MeVis	Medical image processing and visualization
Sculptris	6.0	Pixologic	Digital sculpting and painting program
NETGEN	5.0	NETGEN Team	Tetrahedral mesh generator for 3D geometries

II: Additive manufacturing: The second stage transitions from the digital realm to the physical, using 3D printing techniques. This step fabricates the previously designed digital models of the skull, brain, and cerebral arteries. The process allows for the creation of tangible skull models that replicate the textures and complexities of the human bone anatomy as well as the models needed for the subsequent life-like recreation of the brain and cerebral arteries in step IV. All additive manufacturing processes in this work were executed on a desktop 3D printer with dual extrusion (Raise3D Pro2, www.raise3d.com) using standard 1,75 mm filaments.

III: Material research: The third stage is centered on material science. Here, extensive research is conducted to identify materials that not only mimic the mechanical properties of human tissue but also respond accurately to the surgical tools used during microsurgery. Neurosurgical expertise is employed to identify materials that mimic the tactile properties of the living brain as encountered in real-life surgical procedures. Rheological measurements are critical to ascertain the flow and deformation behavior of the materials, ensuring they behave similarly to biological tissues under stress and manipulation.

IV: Crafting and casting: The final stage involves the casting and crafting process of critical anatomical features of the model such as the Sylvian fissure, cerebral meninges, cerebral arteries, and aneurysms. The manufacturing techniques must be cost- and time-efficient yet precise and tailored to produce the delicate structures relevant during the procedures.

2.2.1 Construction of the skull

2.2.1.1 Digital reconstruction and post-processing of the skull

The patient's CTA imaging dataset served as a basis for the segmentation and digital reconstruction of the skull. The advantage of CTA compared to traditional CT imaging lies in its capability to render a comprehensive reconstruction of the head, encompassing the facial bones and cavities. Crucially, it accurately depicts the lateral skull base, a complex anatomical region delineating the brain from the ear and upper neck.

After downloading the CTA dataset in DICOM (Digital Imaging and Communications in Medicine) format, the open-source reconstruction software InVesalius (InVesalius 3, Centro de Tecnologia da Informação Renato Archer (CTI)), was used for further segmentation. For that purpose, the bone structures were segmented by their greyscale boundaries to create a 3D model of the skull (**Fig. 2**). The generated 3D mesh can be converted into .obj (Wavefront .obj) and .stl (Stereolithography) file formats for further processing.

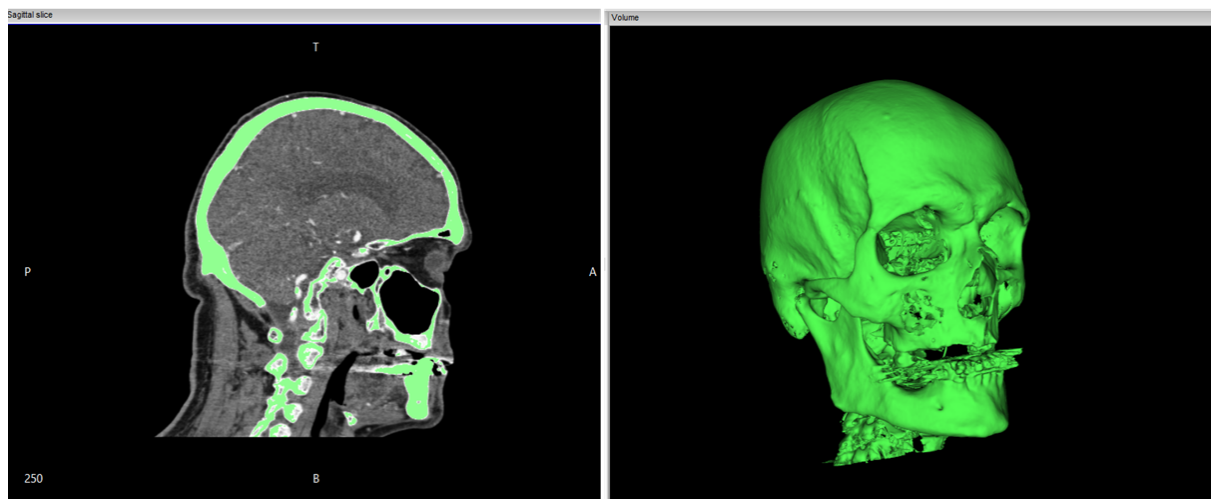


Figure 2: Segmentation and volumetric reconstruction of the head with InVesalius3 defined by greyscale boundaries.

The objective of the digital post-processing was to improve the model's practicability and realism while reducing complexity and manufacturing costs. Initial optimization of the 3D surface mesh was performed with the digital post-processing tool Blender 3.1 (Blender Foundation, community, www.blender.org) to improve quality and reduce artifacts.

The skull model was then further modified with the 3D creation and modeling software MeshMixer 3.5 (Autodesk MeshMixer, Autodesk Inc. www.meshmixer.com) to reduce production costs and time expenditure by incorporating reusable and replaceable parts for cyclic utilization.

A combination of sliding and plug-in mechanisms was designed with MeshMixer and Autodesk Fusion 360 (Autodesk Inc, www.Autodesk.com) and embedded into the model to allow for the removal and reattachment of the lateral skull segments to the reusable parts of the simulator and to improve the

overall stability of the model via a stable three-point fixation. For additional stabilization purposes, two perpendicular supporting wall elements which also function by slide and plug-in mechanism, were constructed, and added to the reusable middle skull base (**Fig. 3**).

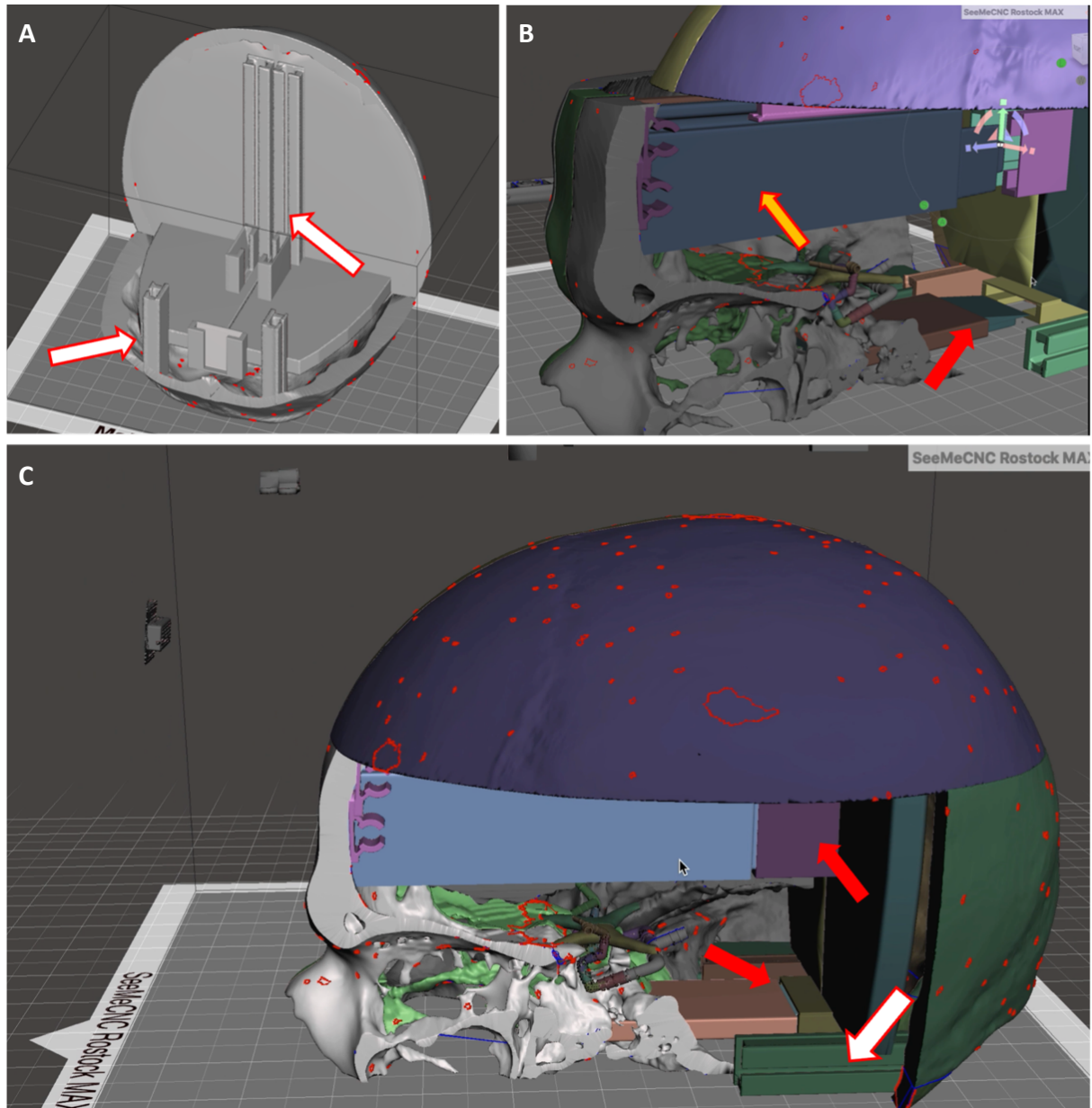


Figure 3: A, B) Reusable calvaria, occiput and central console of the skull with an integrated rail-slide system (white arrows), supporting wall elements (yellow arrows) and plug-in mechanisms (red arrows) for attachment and stabilization of the model. C) Additional plug-in and rail-slide mechanisms integrated into the replaceable skull base elements for swift de- and reattachment of the skull base elements containing the Sylvain fissure and MCA aneurysm models.

Relevant anatomical structures and landmarks that were missing in the initial 3D mesh of the skull, such as the optic nerves and the anterior clinoid process, were manually designed in Meshmixer and Blender and incorporated into the simulator's reusable center console. (**Fig. 4**)

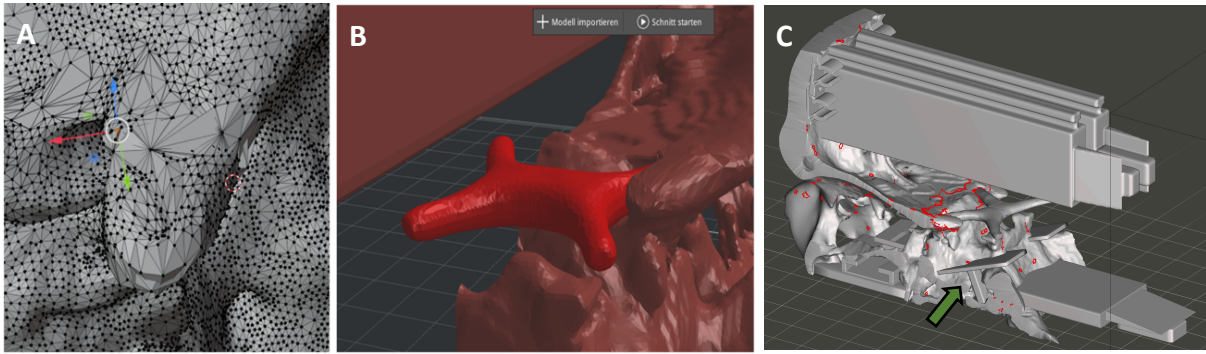


Figure 4: A) Manual digital reconstructions of the anterior clinoid process and B) the optic chiasm in Blender and Meshmixer C) integration of the optic chiasm and supporting socles for the placement of the CAW (green arrow) into the center console of the simulator.

2.2.1.2 Additive manufacturing of the skull

For the fabrication process of osseous structures, the reconstructed and modified data files were exported as .stl files. All 3D printing processes were performed utilizing a Raise3D Pro2 dual extrusion desktop 3D printer (Raise 3D Technologies, Irvine, California, United States, www.raise3d.com). The skull components were manufactured employing 1.75 mm thick white PLA filaments produced by 'Prima', with a predetermined layer height of 0.25 mm and infill density established at 15%. To simulate the disparities in rigidity between compact bone and cancellous bone (diploe) found in the natural cranial bone, the infill density of the skull model was adjusted the 3D slicing software IdeaMaker 4.2.3, (Raise 3D Technologies, Inc., www.raise3d.com) (**Fig. 5**). All components were printed at a consistent temperature of 195 °C (Celsius). The heated bed was continuously maintained at 60 °C to reduce warping, enhance adhesion to the printing mat, and improve interlayer filament bonding.

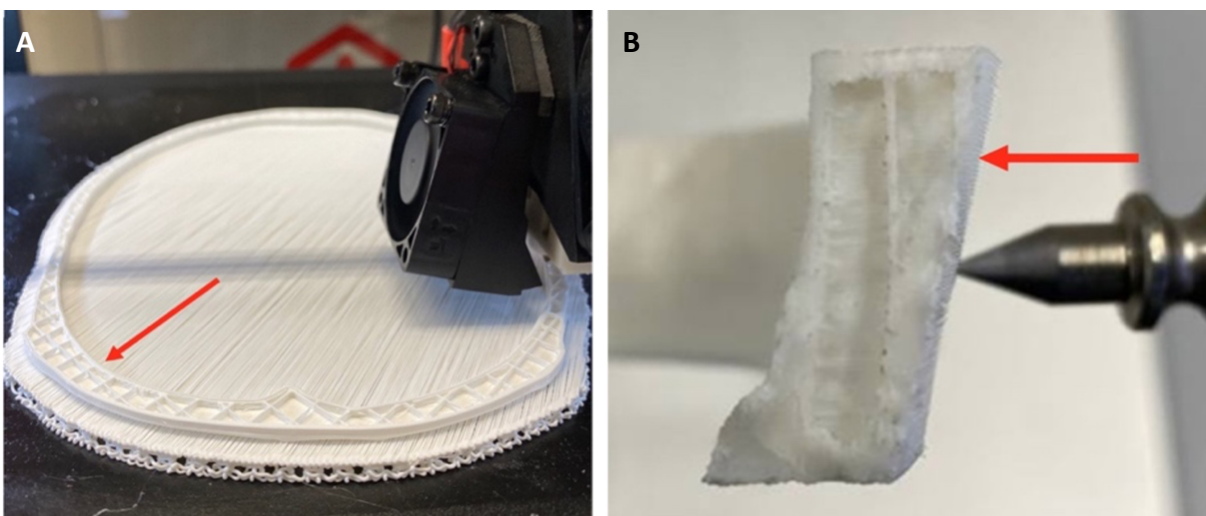


Figure 5: Modifications to the filler density of the 3D printed skull (red arrows) with A) 5% and B) 15% allowing the realistic tactile feedback of the tabula externa and interna during the drilling simulation.

2.2.1.3 Skull model: reusable parts

The core segment of the simulator is constituted by the reusable central console, which fulfills a crucial role as an anchoring point for the replaceable cranial base components and as a connective structure to the calvaria and the occipital region. It encompasses important anatomical structures such as the anterior clinoid processes and the optic chiasm, which serve as indispensable landmarks for the surgical procedure. Additionally, the console features a plateau designed to accommodate the CAW model. Clip mechanisms for attaching and securing the replaceable cranial base elements to the central console are situated at both the anterior edge and the base of the central console (**Fig. 6 A**). The central console can be affixed to the calvaria and the occipital region via the incorporated rail and clip mechanisms (**Fig. 6 B**).

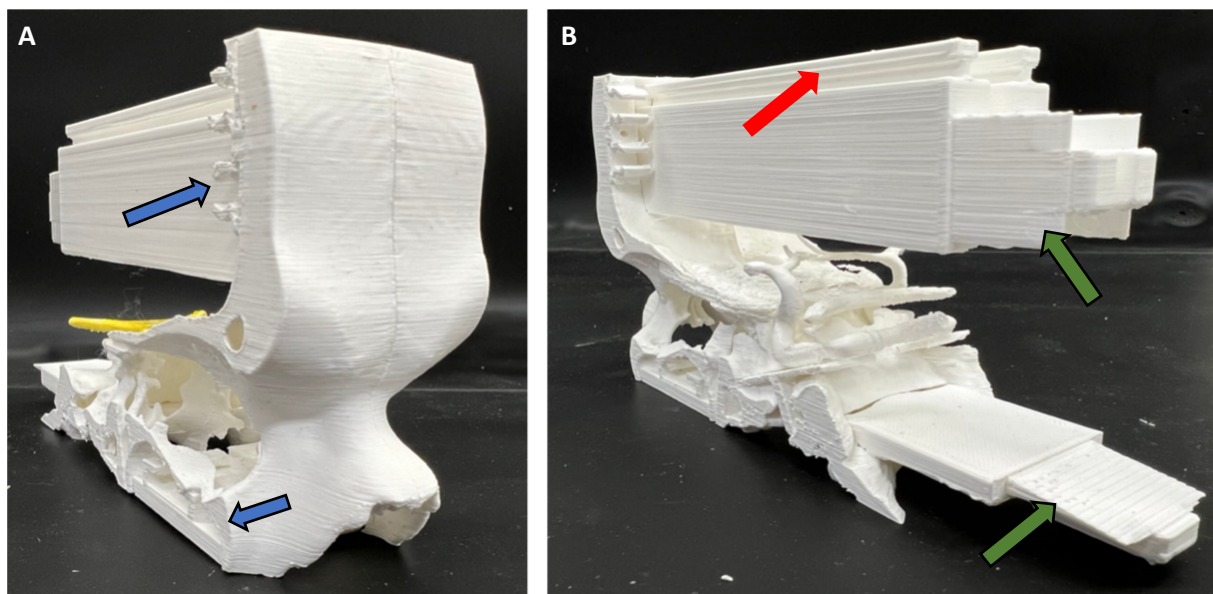


Figure 6: A) The reusable central console serves as an anchoring and connecting point for the replaceable skull base parts via clip mechanism at its anterior edge and base (blue arrows) B) the reusable calvaria and occipital region can be attached via plug-in mechanisms (green arrows) and an integrated slide and rail system (red arrow).

The predominant osseous component of the simulator is composed of the calvaria and the occiput, which are reusable and necessitate a singular, comprehensive print. Utilizing the integrated rail and clip mechanisms, a straightforward and robust three-point fixation can be achieved in conjunction with the central portion and the replaceable cranial base segments. The selected infill density of the 3D print enables the simulation of the anatomical and haptic properties of the cranial bone, particularly the external lamina, diploe, and the internal lamina. Beneath the osseous structure of the calvaria and occiput, vacant spaces exist that may be employed for the facultative incorporation of a

pumping mechanism. The result of the reusable top and back structures of the simulator are depicted in Figure 7.

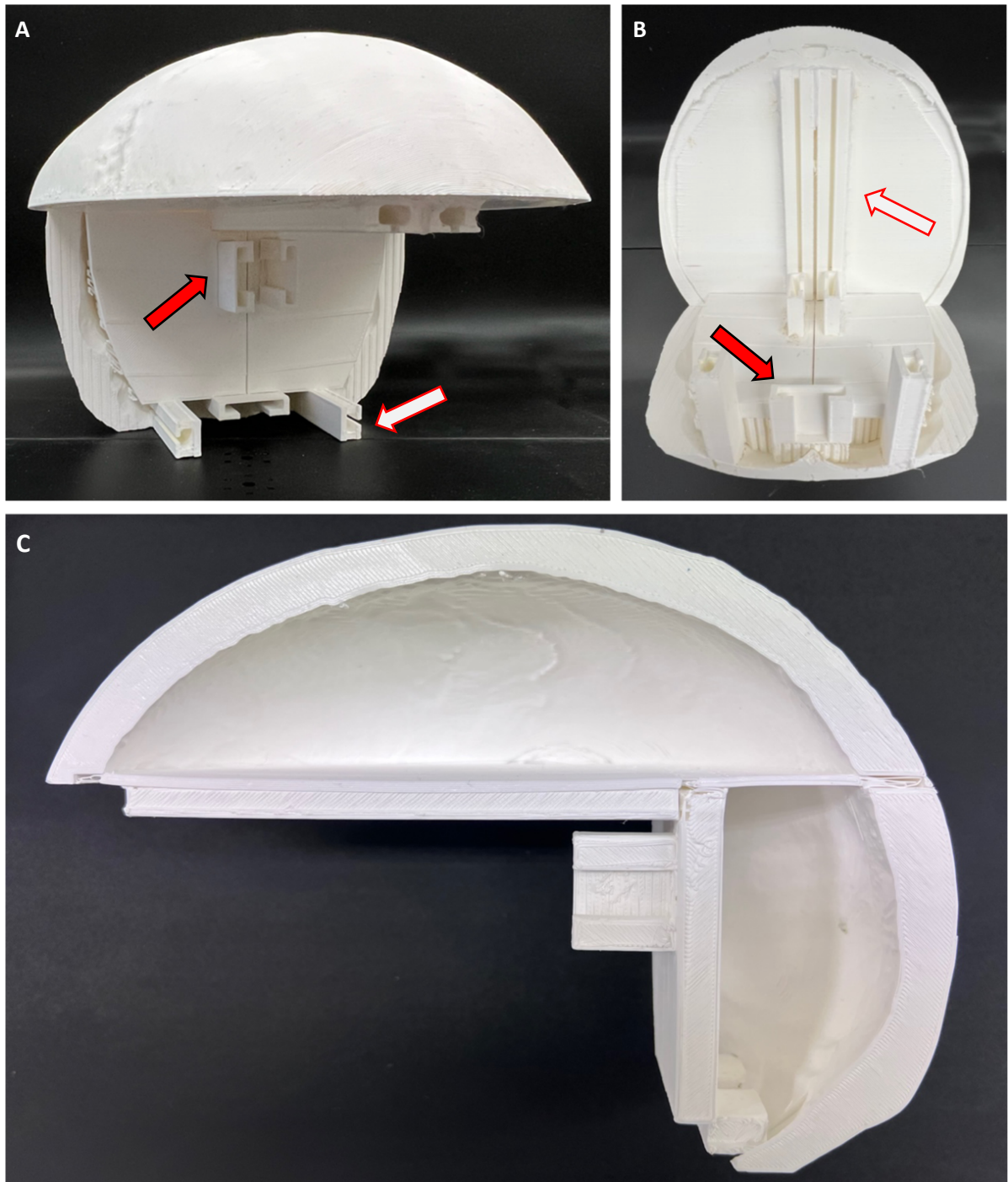


Figure 7: A, B) Results of the reusable calvaria and occiput with integrated slide (white arrows) and plug-in mechanisms (red arrows) for attachment of the replaceable skull parts C) empty spaces in in the frontoparietal and occipital parts of the reusable skull for optional integration of a peristaltic pump.

2.2.1.4 Skull model: replaceable parts

The substitutable cranial base elements of the simulator encompass the essential anatomical osseous formations required for planning and carrying out a pterional craniotomy. The design facilitates a decrease in both, material expenses and 3D printing duration, while incorporating the essential osseous structures, sutures, and landmarks indispensable for the planning and execution of a pterional craniotomy. Moreover, it permits the variation of the surgical approach beyond the pterional craniotomy, including the mini-pterional, subtemporal, and lateral supraorbital techniques. To affix the model to the central console, clips are situated at the base and anterior, medial portions of the model. For supplementary attachment to the occiput, a rail model is employed, as illustrated in **Figure 8**.

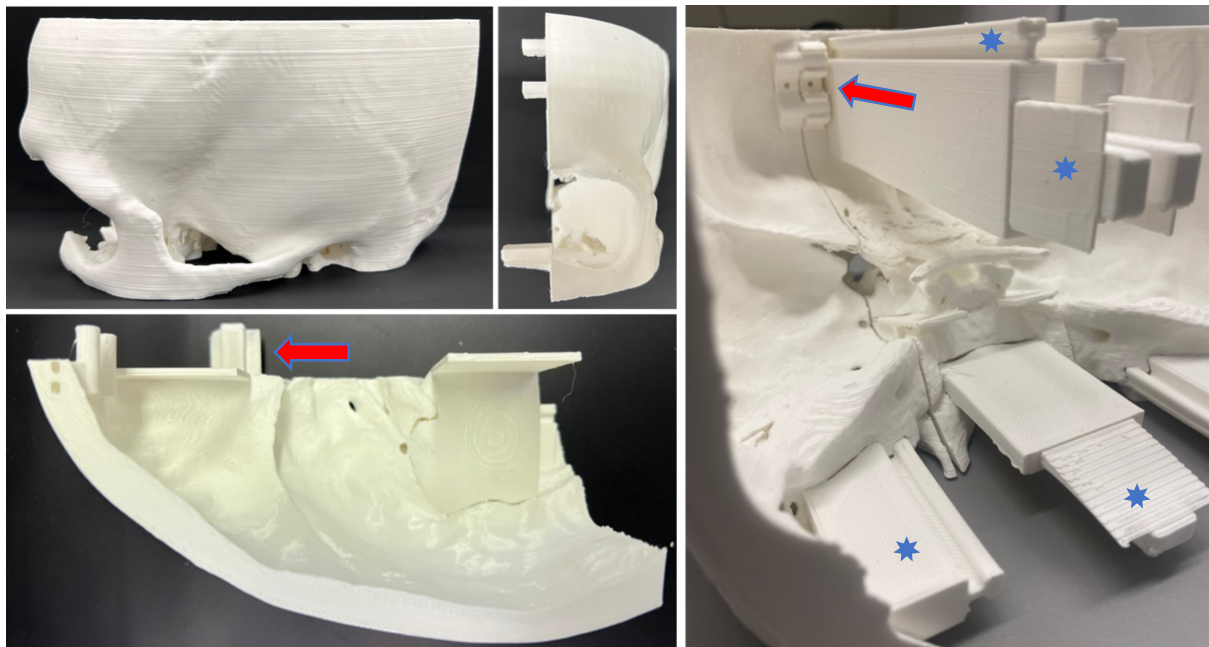


Figure 8: Results of the replaceable skull base elements with connective structures for a stable three-point attachment via clip and slide-rail mechanisms to the phantom's central console (red arrows), the calvaria and occiput (blue stars).

2.2.2 Construction of the Sylvian fissure

2.2.2.1 Segmentation and digital post-processing of the brain

As presented in Figure 1, high-resolution T1-weighted MRI scans of the patient served as a basis to perform whole brain reconstruction with FreeSurfer V6 (Martinos Center for Biomedical Imaging, Harvard University, Cambridge, Massachusetts, USA, <https://surfer.nmr.mgh.harvard.edu>), an open-source software package for anatomical segmentation and cortical surface reconstruction.

The Linux-based Virtual Machine performs a subcortical volumetric segmentation and cortical reconstruction completed with an automated algorithm able to distinguish between brain and non-brain tissue, creating a precise three-dimensional model of the brain's pial surface (**Fig. 9**). The segmentation and reconstruction of the whole brain with FreeSurfer does not require any user interaction and can take up to six hours.

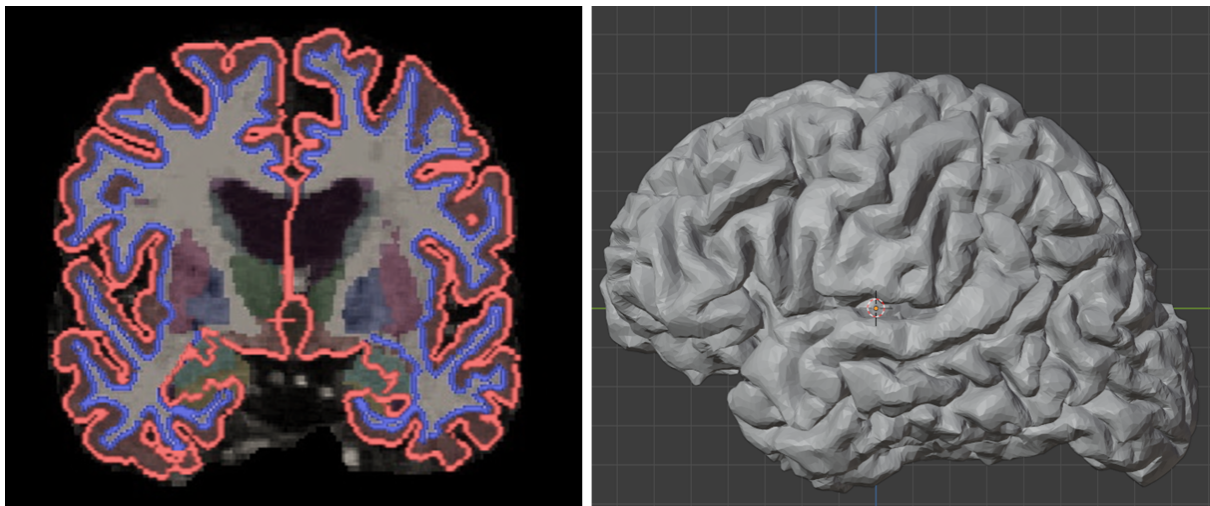


Figure 9: A) Pial surface segmentation of the brain in FreeSurfer B) reconstructed 3D mesh of the brain in Blender.

Subsequently, the reconstructed 3D mesh of the brain was converted into a .stl standard 3D file format for further image processing. Analogous to the skull model, the 3D mesh of the brain was sectioned to focus on the region surrounding the lateral sulcus, ensuring optimal fitting within the skull model, and maximizing the reduction of material costs and production time. While the automated segmentation with FreeSurfer is adequate for capturing the cortical surface of the brain, reconstructing deeper sulci, specifically the Sylvian fissure, necessitates supplementary manual segmentation.

The challenge entailed accurately replicating the lateral sulcus between the temporal, parietal, and frontal lobes to generate an anatomically precise negative mold for casting the Sylvian fissure. This process needed to fulfill two crucial criteria:

1. The 3D model was meticulously designed to allow for the infusion of silicone into the sulci, particularly encompassing the Sylvian fissure. This procedure is paramount to ensuring the anatomical fidelity of the model and enhancing the overall simulation quality, as it facilitates the essential process of delineating the Sylvian fissure in the casted model.
2. Following the creation of the negative silicone mold, the 3D printed model had to be removed without damaging the silicone mold, particularly in areas vital for the simulation, such as the lateral sulcus and frontal operculum.

To meet these requirements, the 3D mesh of the Sylvian fissure was further processed in Blender. The mesh was meticulously divided into two segments, determined by hand-selected points demarcating the pial surfaces of the temporal and frontal lobes within the sulcus (**Fig. 10**).

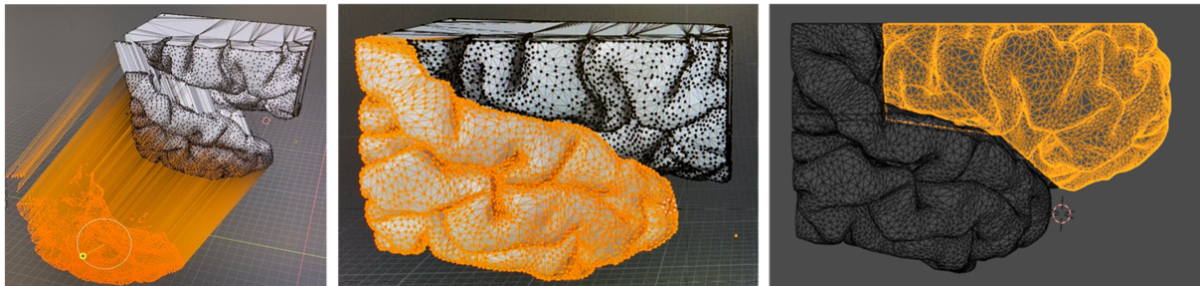


Figure 10: Surface mesh of the Sylvian fissure divided into temporal and frontal lobes in Blender.

2.2.2.2 Additive manufacturing of the Sylvian fissure model

Analogous to the 3D printing process of the skull, the reconstructed and digitally post-processed files of the Sylvian fissure model were exported as .stl files.

The printing of the Sylvian fissure as a 3D model was a challenging process involving a variety of configurations and filament types with the purpose of facilitating the negative silicone molding process and meet the criteria stated in section 2.2.2.1. (**Fig. 11**)

For this purpose, the models were initially “hollowed out” with the third-party 3D slicing software ChituBox 1.9.3 (CBD Technology Co., Ltd., www.chitubox.com) to reduce printing time and expenditure. The models were then 3D printed using water-soluble PVA (Polyvinyl alcohol) and thermoplastic PETG (Polyethylene terephthalate glycol) filaments. However, both approaches did not produce the desired anatomical accuracy and were therefore abandoned.

The Sylvian fissure model, that was ultimately used for the negative silicone molding process was printed in two parts, as delineated in section 2.2.2.1, using 1.75 mm thick white PLA filaments by Prima (PrimaSelect) at 195 °C. The heat bed was constantly tempered 60 °C.

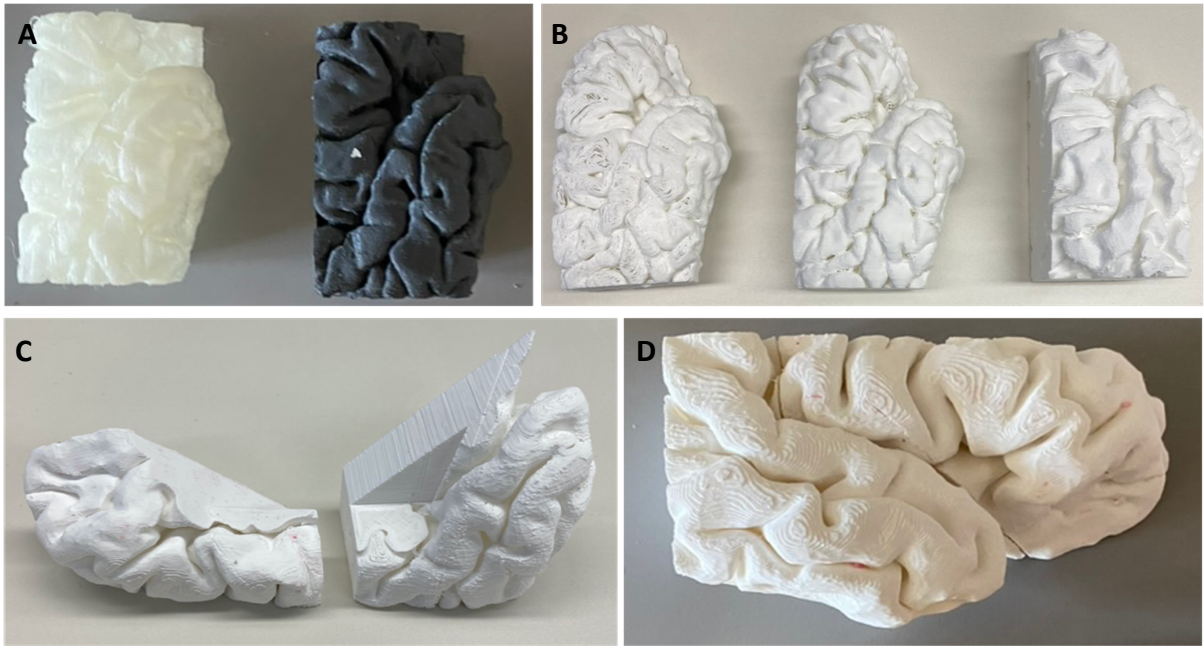


Figure 11: A) 3D printed models of the Sylvian fissure in varying configurations and densities printed with PVA, PETG and B) PLA-filaments C, D) models of the Sylvian fissure separated in frontal and temporal lobes to ensure anatomical accuracy of the negative silicone form.

2.2.2.3 Substudy on simulating the living brain

In a previous investigation, a diverse array of materials at various concentrations was examined to determine those with the highest haptic similarity to genuine brain tissue.³⁶ The study involved the input of seasoned neurosurgeons and relied on rheological measurements, ultimately concluding that 12.5% concentration of gelatin Bloom 260 most closely replicated the tactile qualities of living brain tissue. Despite the advantages of gelatin-based models over existing alternatives, such as cadaveric simulations, certain limitations were observed, including the softening of the material after 5 - 7 days, the requirement for refrigeration, and ethical concerns related to sourcing from animal bones and skin. This research was further developed by comparing gelatin Bloom 260 to alternative materials with similar tactile properties such as candle gel, polyvinyl alcohol, and polyacrylamide in distinct concentrations (**Table 2**).

Table 2: Material samples and concentrations tested and rated by experienced neurosurgeons regarding their resemblance to the tactile properties of the living brain as encountered during surgical procedures.

Material	Sample name	Concentration
Gelatin Bloom 260	NC-73	7.5%
	MC-26	12.5%
	AX-47	17.5%
Candle gel	ZN-28	100%
Polyvinyl alcohol (PVA)	BN-56	Hydrolysis: 27,5%
		32,5%
		37,5%
Polyacrylamide	HQ-79	12%

For the subjective evaluation of the materials, testing samples of the materials in differing concentrations (gelatin Bloom 260) and degrees of hydrolysis (PVA) were generated using a simplified and minimized SF negative silicone mold (**Fig. 12**). Two neurosurgeons with extensive experience in neurovascular and neurooncological surgery independently tested each specimen with and without microsurgical instruments and provided their assessment of each specimen without knowledge of the material or concentration contained within. The test materials were subsequently ranked in five categories based on their tactile characteristics in relation to authentic living brain tissue and reusability:

Consistency - Resistance - Elasticity - Reusability – Texture

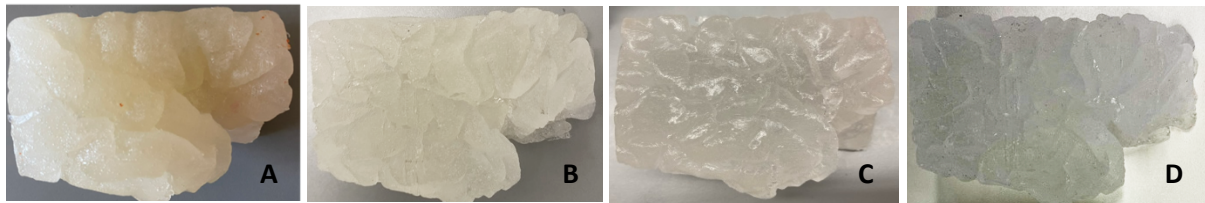


Figure 12: Testing samples of the Sylvian fissure model casted with A) gelatin Bloom 260 in 12,5% concentration B) Polyvinyl alcohol with 32,5% degree of hydrolysis C) polyacrylamide in 12% concentration and D) candle gel.

According to the evaluations of the experienced neurosurgeons, transparent candle gel emerged as the most suitable material for emulating the tactile properties of the living brain tissue as encountered in real-life settings (**Fig. 13**).

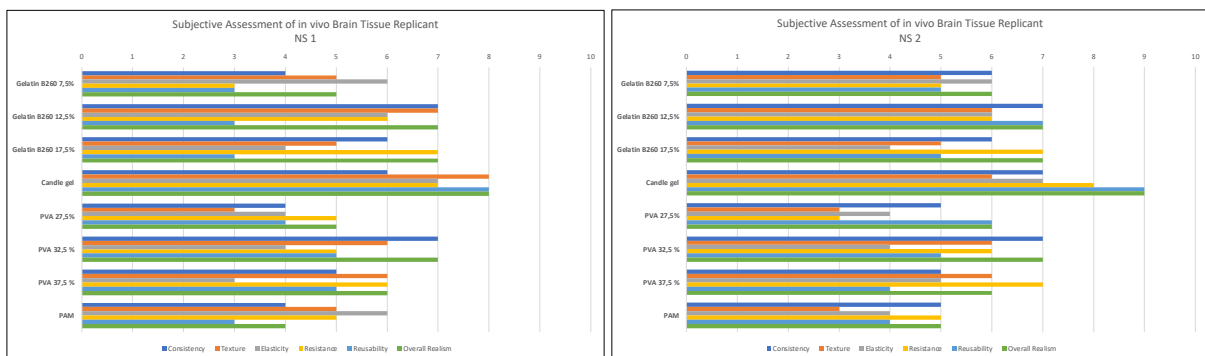


Figure 13: Results of the subjective assessment of tested materials regarding their tactile properties by two experienced neurosurgeons derived from a 10-point Likert scale.

Rheological measurements

To corroborate these findings, rheological testing of candle gel was conducted, and the results were compared to the initial investigation involving gelatin 260 Bloom and the rheological properties of cadaveric brain tissue.^{35,58–60 61}

Sample preparation:

The candle gel was heated up in a water bath and poured into glass Petri dishes. Special care was taken to avoid producing bubbles inside the candle gel. After removing the gel candle from the Petri dishes, it was sliced into cylinders with 35 mm and 25 mm diameter using a cutter (**Fig. 14**).

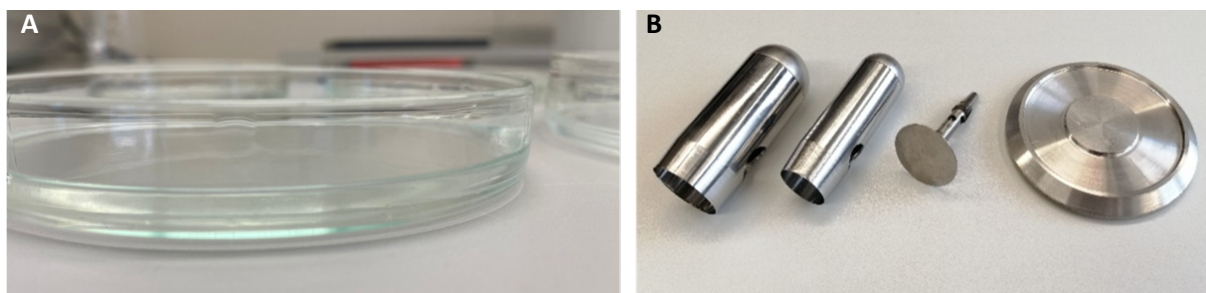


Figure 14: A) bubble-free samples of candle gel with a thickness of 2,5 mm for rheological testing B) 35 mm diameter cutter, 25 mm diameter cutter, 35 mm measuring geometry for cylindrical sample preparation.

Test method

To derive the mechanical material properties of the gel candle, two different tests were performed:

1. Three-cycle compression tests

First, to compare the mechanical characteristics of the candle gel at hand with those of the gelatin samples in different concentrations, three-cycle compression tests with a frequency of 0.1 Hz were performed using the Bose Electroforce System 3200 (BOSE Corporation, Framingham, Massachusetts, United States, www.bose.com) (**Fig. 15 A**).

- Testing protocol for three-cycle compression tests:

The candle gel samples were placed on the lower surface of the device, which is connected to the load sensor (**Fig. 15 B**). To facilitate the comparison of the results with previous findings using gelatin 260 Bloom, -0.2 - 0.6, and -1.2 kPa (kilopascal) normal stress tests were applied to the samples. It should be noted that the stretch and stress parameters were derived using the following relations:

$$\text{stretch} = \frac{L_t}{L_0} = \frac{L_0 + \Delta L}{L_0} = 1 + \frac{\Delta L}{L_0} = 1 + \varepsilon$$
$$\sigma = \frac{F_{axial}}{A_0}$$

where L_0 is the initial length of the sample, L_t is the length of the sample after applying the axial force, ΔL is the change in the length of the sample after applying the force, ε is the strain of the sample, σ is the stress, F_{axial} is the axial force, and A_0 is the initial cross-section area of the samples.

2. Rotary shear rheology tests

For further characterization of the mechanical properties of candle gel, rotary shear rheology tests were performed. The experiment was carried out at 26 °C room temperature using a HAAKE MARS Rheometer (Thermo Fisher Scientific Inc, Waltham, Massachusetts, United States, www.thermofisher.com) with a parallel-plate system (**Fig. 15 C**).

- Testing protocol for rotary shear rheology:

The prepared samples had a 35 mm diameter and thickness of 2,5 mm. The samples were placed on the lower plate of the rotary shear rheometer (**Fig. 15 D**). To ensure contact between samples and

prevent the sample from slipping, a 0.6 N (Newton) normal force was applied to the upper plate. To derive the mechanical properties, in particular the storage, loss modulus, and phase angle of the samples, stress sweep tests were performed. Storage modulus could be related to the amount of energy the case under study gives back when it undergoes deformation. The amount of energy that cannot be discovered from the case under study is the energy lost to friction and internal motions, which is expressed as the loss modulus and referred to as the viscous or imaginary modulus. The phase angle is also called damping and is an indicator of how efficiently the material loses energy to molecular rearrangements and internal friction. It is also the ratio of the loss to the storage modulus and therefore is independent of geometry effects.^{62,63}

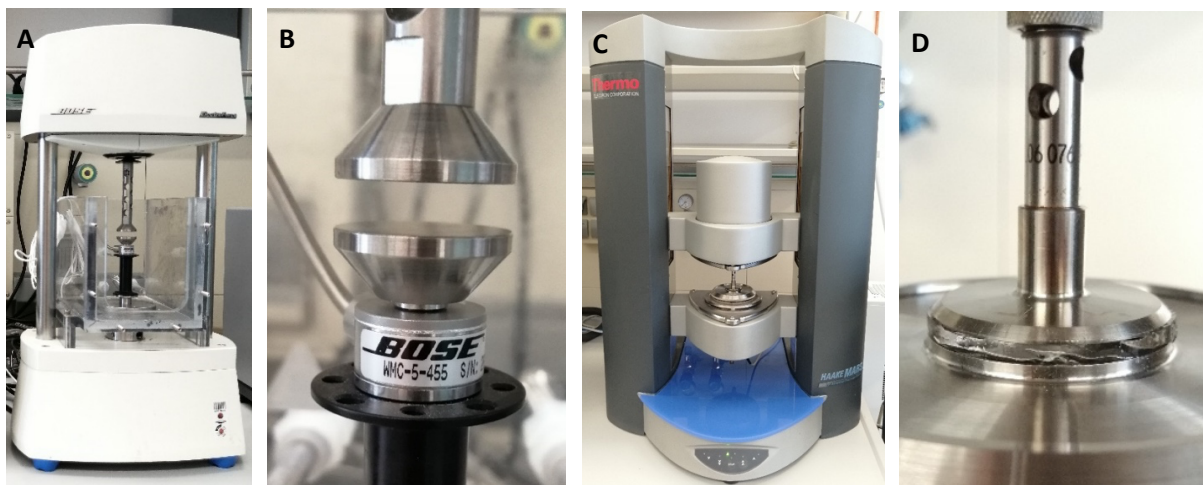


Figure 15: A) Bose Electroforce System used for three-cycle compressions tests B) candle gel samples were placed on the lower surface of the device, which is connected to the load sensor C) rotatory shear rheological measurements were executed on the Thermo Scientific HAAKE MARS rheometer D) candle gel placed between measuring geometry and lower plate of the rheometer.

For investigating the effect of frequency and the elapsed time on the results presented through the stress sweep test, additional frequency sweep analysis as well as relaxation tests were performed:

- Stress sweep test (response to torque/shear stress)

In this test, a sinusoidal oscillating torque and consequently sinusoidal oscillating shear stress are applied to the samples. After deriving the storage and loss modulus at each step, the amplitude of the applied torque/shear stress is increased, and the test is repeated until the torque/shear stress reaches a pre-defined value. In this test, a constant frequency of 1 Hz (Hertz) and stress amplitudes from 0.1 to 5000 Pa (Pascal) were considered.

- Frequency sweep test (response to frequency)

To investigate the effect of oscillation frequency during the test on the results, a frequency sweep analysis can be performed. In this test, the amplitude of the applied torque/shear stress is kept

constant, while the oscillating frequency is increased. A stress amplitude of 0.1 Pa and 100 Pa with varying frequencies (0.01 Hz - 10 Hz) were applied to the samples.

- Response to time (relaxation test)

In this test, the frequency, applied torque/shear stress, and temperature is kept constant for a definite time and the possible changes in the mechanical properties of the sample are investigated. A stress amplitude of 10 Pa, a frequency of 1 Hz at a temperature of 26 °C were considered for this test.

Results of the rheological analysis

- Stretch versus stress test

The results of the stretch vs. stress graphs are presented in **Figure 16**. If the maximum stretch in different gelatin samples is compared with different concentrations as presented in **Table 3**, it becomes clear that at the specified compression stress of -1.2 kPa, the candle gel has higher stretch values in comparison to other materials considered. Noting the fact that in the case of compression strain values are negative and taking the strain-stretch relations into account, it can be concluded that candle gel has lower strain values in comparison to other materials tested and consequently has a higher storage modulus and is therefore stiffer than the samples with specified gelatin Bloom 260 concentrations.

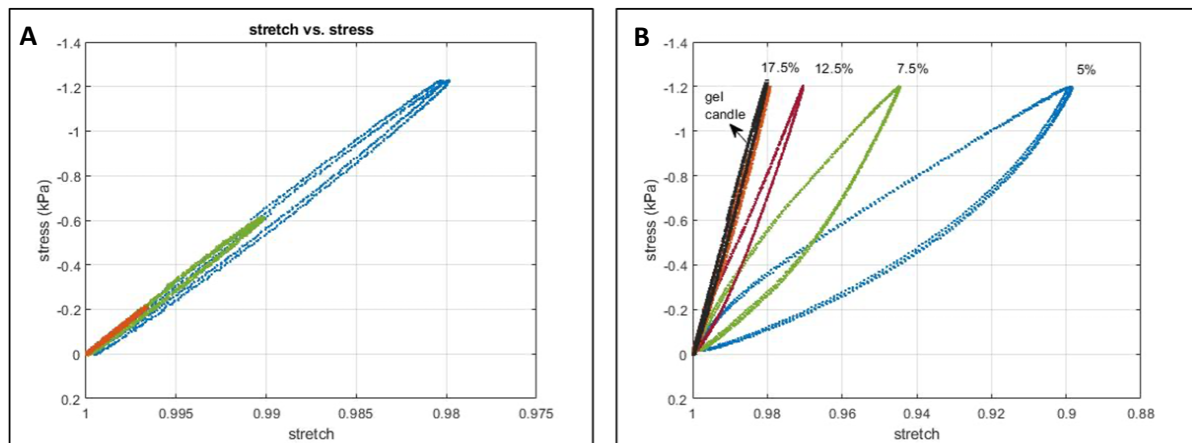


Figure 16: A) Stretch vs. stress results derived by implementing compression stresses of (a) 0.2 kPa, (b) 0.6 kPa, and (c) 1.2 kPa on candle gel samples B) stretch vs. stress results of candle gel compared to the results of gelatin 260 Bloom samples in 5%, 7.5%, 12.5%, and 17.5% concentrations.

Table 3: Stretch of different samples in comparison to gel candle after applying 1.2 kPa compression stress.

Diameter (mm)	Storage modulus (Pa)	Loss modulus (Pa)	$\tan(\delta)$
35	3019.0	114.1	0.038

- Frequency sweep and relaxation tests:

The outcomes from the frequency sweep test and the relaxation test show that in the presented case the mechanical properties of the samples are not dependent on the time and frequency in the specified ranges mentioned previously. The storage modulus, loss modulus, and tangent of phase angle, derived by performing the stress sweep test, are presented in **Figure 17**. The parameters in the linear viscoelastic region along with the average thickness of the samples are presented in **Table 4**.

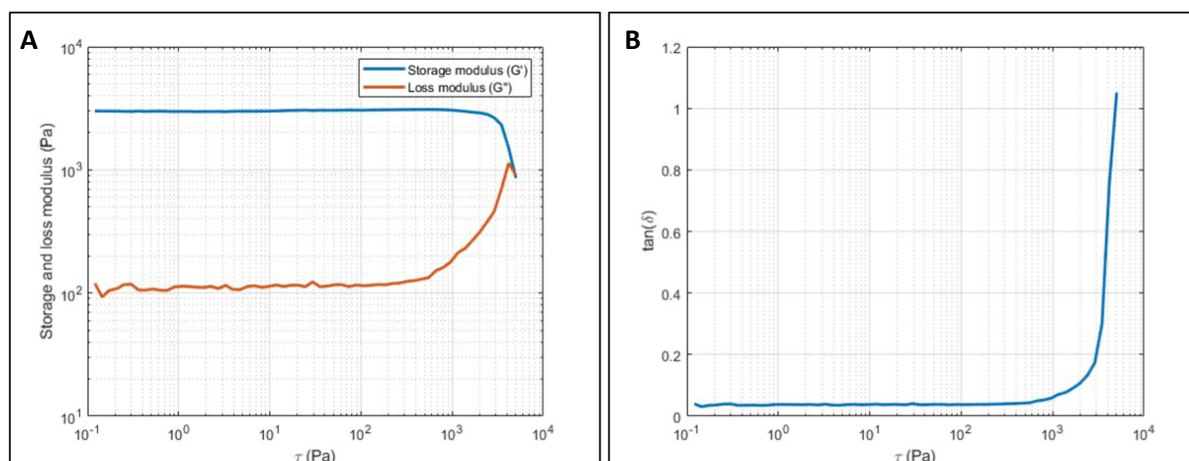


Figure 17: A) Storage and loss modulus B) tangent of the phase angle.

Table 4: Dimensions, weight, and mechanical properties of the sample in the linear viscoelastic region.

Material	Candle gel	Gelatin 17.5%	Gelatin 12.5%	Gelatin 7.5 %	Gelatin 5%
Stretch at 1.2 kPa	0.980	0.977	0.967	0.942	0.895

Interpretation

The tactile properties of the living brain, as found during neurosurgical procedures can best be evaluated by experienced neurosurgeons. Based on the subjective evaluation of experienced neurosurgeons, candle gel emerged as the most realistic substitute for brain parenchyma regarding the tactile properties of the living brain. The results are comparable to the previous findings using gelatin 260 Bloom in 12,5% concentration. However, while the rheological measurements conducted on candle gel revealed similar mechanical properties in comparison to gelatin 260 Bloom in 12,5% concentration, candle gel is the superior substitute regarding storage, durability, and accessibility. Therefore, based on the subjective evaluation by experienced neurosurgeons and supported by the rheological findings of this substudy, candle gel was chosen for the subsequent casting process of the Sylvian fissure models.

2.2.2.4 Casting of the Sylvian fissure

Doubling silicone (Wagnersil, Wagner Dental GmbH & Co. KG, www.wagnerdent.de) with a resulting hardness of 22 Shore A was used to create a negative mold of the Sylvian fissure. For this, the brain model was covered with form-separation spray (CREARTEC ARTIDEE, www.creattec.de) and placed in a box with removable side panels (**Fig. 18**). After mixing both components of the doubling silicone in a 1:1 ratio, the liquid was poured over the 3D printed model of the Sylvian fissure until it was completely covered. The silicone had a pot life of 5 - 6 minutes and could be easily demolded after 30 minutes. To prevent any tearing of the soft silicone tissue, the model was removed carefully with special respect to the sulcus of the Sylvian fissure. The manufactured negative mold was then used for the casting of the Sylvian fissure models. Thus, 450 gram of candle gel was warmed up to 95 °C in a water bath until the gel was completely liquid. The mold was then filled with the melted candle gel and carefully tapped on a table to release any containing air bubbles. The model was then placed in a refrigerator. After cooling down for 30 minutes, the Sylvian fissure replica could be swiftly separated from the silicone mold.

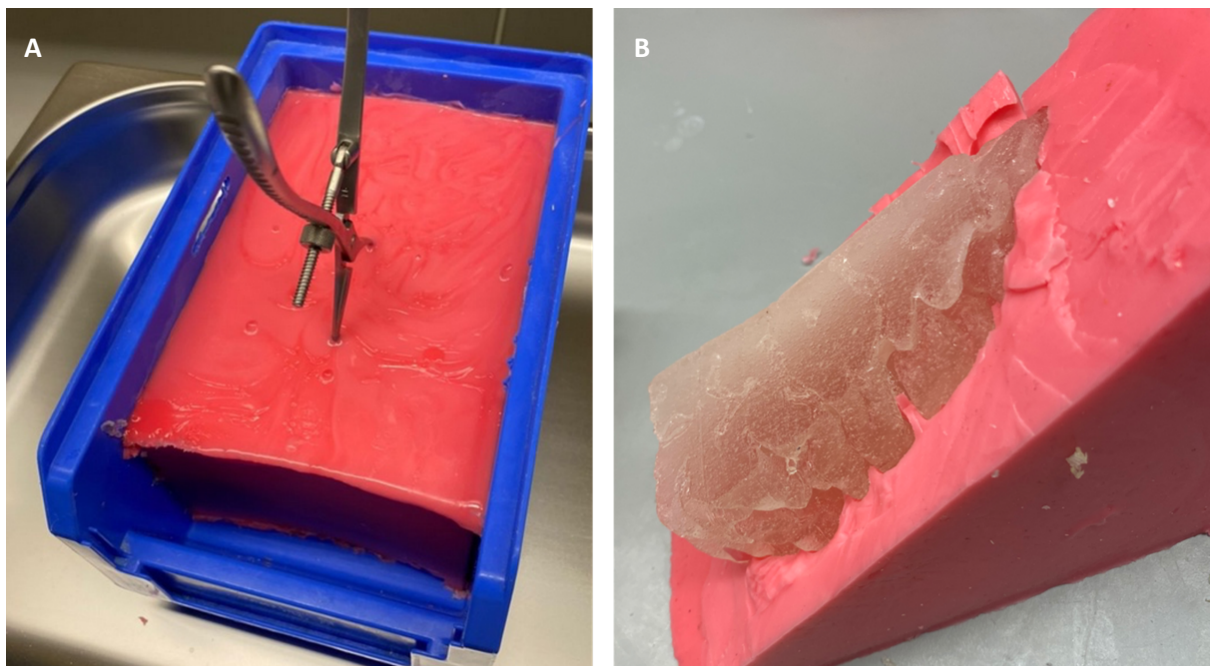


Figure 18: A) Negative silicone mold of the Sylvian fissure model B) candle gel-based Sylvian fissure model ready to use after cooling down for 30 minutes.

The resulting Sylvian fissure model can be observed in **Figure 19**. The meticulous reconstruction of the Sylvian fissure facilitated the creation of a detailed negative silicone mold for the anatomically accurate, haptically faithful casting of the Sylvian fissure in a single pour, allowing the incorporation of the vascular model within the lateral sulcus.

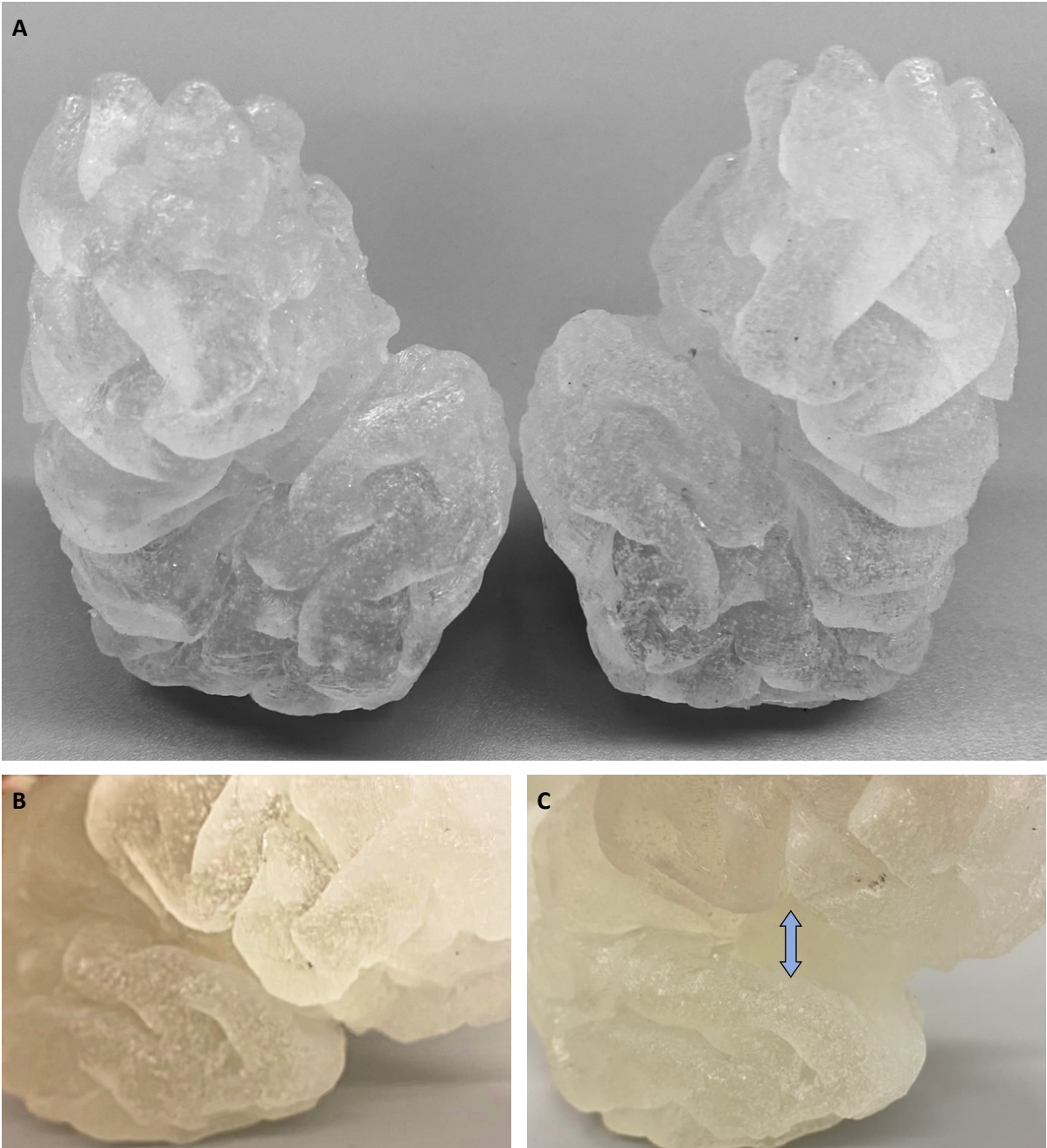


Figure 19: A) Results of the Sylvian fissure casting with candle gel (left and right), revealing high anatomical detail and tactile accuracy B, C) the Sylvian fissure model is casted in a single pour, allowing the temporal and frontal lobes to be retracted (blue arrow) and blood vessels and aneurysms embedded within the Sylvian cistern and lateral sulcus.

2.2.3 Construction of cerebral arteries and aneurysms

2.2.3.1 Segmentation and digital post-processing of the Circulus arteriosus Willisii

Based on the previously established workflow by Saalfeld et al.⁶⁴, initial segmentation comprising the CAW and connected vessels was extracted from the patient's contrast enhanced T1-weighted magnetic resonance tomographic imaging data. Due to the attenuation of the vessels via contrast agent accumulation, there is a sufficient signal contrast between the lumen of the vessels and the surrounding tissue. Therefore, they can be easily segmented by threshold-based techniques, which was performed with the medical image processing and visualization tool MeVisLab 2.6.2 (MeVis Medical Solutions AG, Bremen, Deutschland, www.mevislab.de). Next, the surface of the mesh was smoothed using blender's smooth modifier tool. More detailed corrections on the surface mesh were performed with the 3D modeling and animation tool Sculptris 1.02 (Pixologic, Inc., www.sculpteo.com).

All remaining artifacts were removed using Blender's boolean modifier. Finally, the surface structure was improved with NETGEN 5.0 (NetGen Mesh Creator, www.sourceforge.com), which provides algorithms for advanced optimization of mesh surfaces. After the smoothing of the surface and removal of the artifacts, the 3D mesh of the CAW was hollowed out with ChituBox and further modified in Blender and MeshMixer to allow the optional simulation of blood perfusion and ensure compatibility with the central console with emphasis on anatomical correctness and its spatial relationship to surrounding structures (**Fig. 20**).

The CAW was designed to remain in the center console with connecting interfaces integrated into the proximal M1 segments of the CAW model allowing a swift connection of the MCA models to the CAW without the need to disassemble the simulator entirely.

2.2.3.2 Additive manufacturing of the Circulus arteriosus Willisii

With the digital reconstruction, a hollow 3D model of the CAW was printed using 1.75 mm thick white PLA filament. The model was modified to allow the simple attachment and replacement of the aneurysm models by magnets. The layer height was set to the printer's minimum of 0.01 mm to replicate the small arterial branches as precisely as possible. The printing temperature was set at 201 °C on a tempered heat bed at 65 °C.

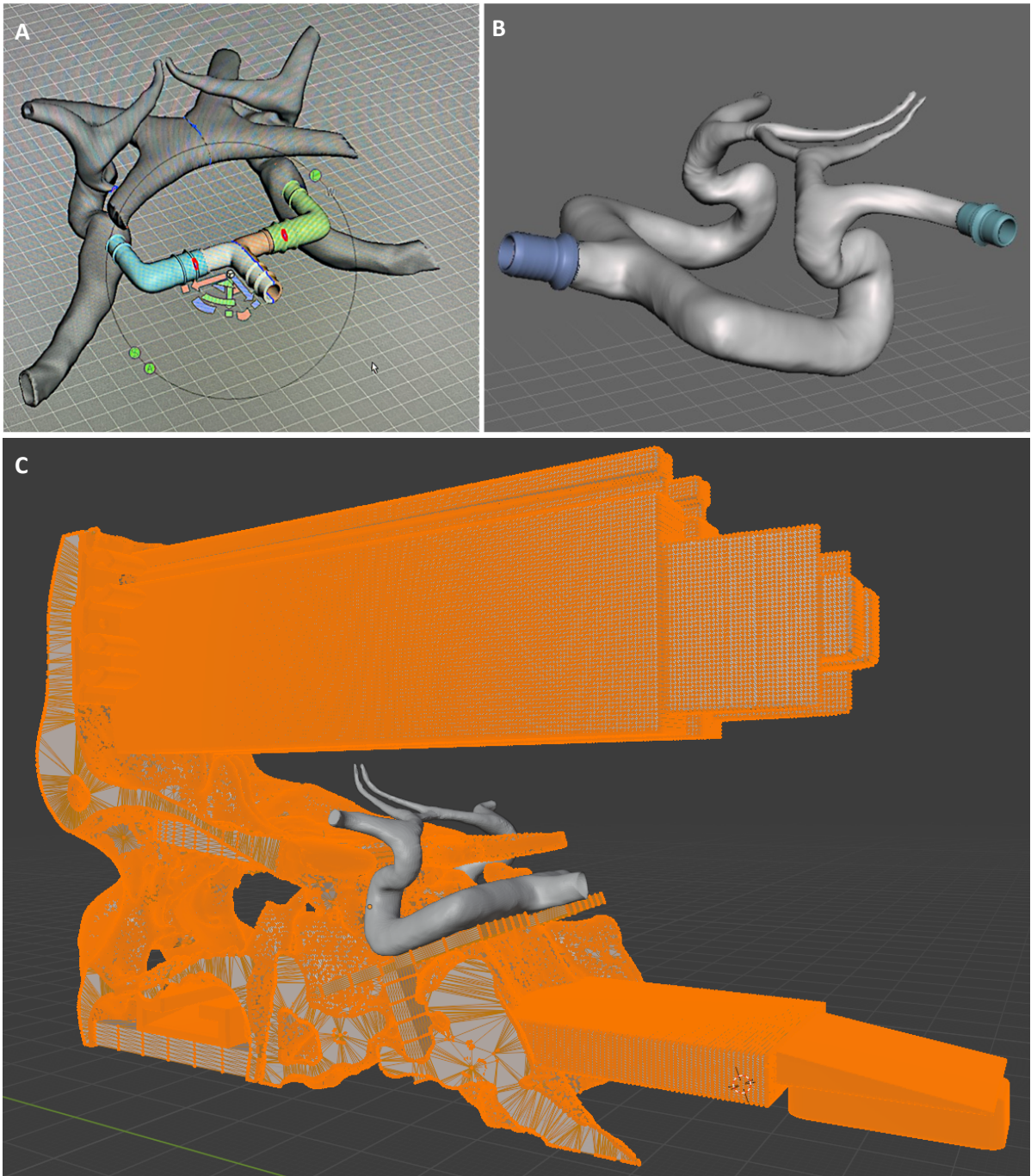


Figure 20: A, B) Reconstruction and digital post-processing of the CAW in Meshmixer and Blender with integrated connectors for quick magnetic attachment and replacement of MCA aneurysms C) modified CAW placed into the center console.

2.2.3.3 Modeling of the Circulus arteriosus Willisii

The 3D printed model of the CAW was coated with red liquid latex (Lilatex, www.lilatex.de) up to three times. For better adhesion of the latex to the printed PLA model, the surface was brushed with a latex coalescing agent (ARTIDEE Creartec latex coalisator) before and after each coating process. After drying for 20 minutes, the magnetic adapters were attached on both sides to the reconstructed interface located at the proximal M1 segments.

The finished model is a hollowed-out, latex-coated vascular construct exhibiting precise anatomical representation of the distal internal carotid arteries, as well as the anterior circulation encompassing the middle and anterior cerebral arteries, in conjunction with the anterior communicating artery. To facilitate swift attachment and replacement of the MCA aneurysms, small cylindric adapters containing magnets were added on both sides of the CAW model at the proximal M1 segments.

The results of the CAW reconstruction can be observed in **Figure 21**.



Figure 21: A) Hollowed-out 3D printed model of the CAW B) latex-based CAW model (earlier version) C) finished CAW model coated with latex and embedded in the central console with magnetic adapters attached on both proximal M1 segments.

2.2.3.4 Modeling of MCA bi-/trifurcation aneurysms

While the following methodology can be used to create any patient-specific cerebral aneurysm, initially a set of five MCA aneurysms were designed based on morphological features which influence the techniques of clipping as described in the literature.⁶⁵⁻⁶⁹ All aneurysms were placed at the bi-/trifurcation of the middle cerebral artery. Using the digital reconstructions as 3D printed templates, each aneurysm model was manufactured individually by hand. As a skeleton, a model of the middle cerebral artery and its branches was built using a wire with 0,65 mm in diameter. For detailed modeling, melted candle wax with a melting point of 58°C was used. The model was then dipped into the liquid wax until all main branches had a diameter of approximately 0,5 cm. The individual templates were then used to adapt the width of each branch and subtracted 2 mm for the vessel wall. The modeling of the aneurysms was performed separately by using candle wax that had been heated up and formed into the desired aneurysm shape by hand (**Fig. 22**). Details of the aneurysm were carved into the model using a scalpel. Smoothing eventually rough surfaces and adapting the size of the aneurysm were achieved by heating the wax with a standard lighter. The finished aneurysm models were attached to the MCA template using a thin piece of wire. Using a small paintbrush, the wax model was covered with latex coalescing agent by CREARTEC (ARTIDEE www.creattec.de) to achieve a better adhesion between wax and latex. The wax model was then dipped into a small container filled with red liquid latex by Lilatex. The coating process was repeated until the model was covered with four thin layers of latex before leaving it to dry in room temperature for 2 hours.

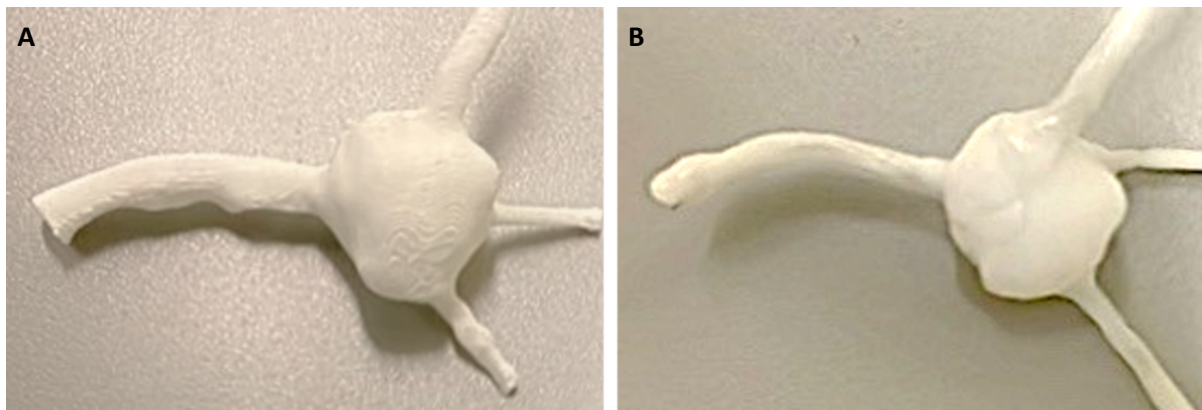


Figure 22: A) 3D printed template of an MCA trifurcation with giant aneurysm B) hand-crafted candle wax model.

The model was then bathed in hot water with a temperature of 65 °C which is higher than the melting point of the candle wax at 58 °C but also cool enough to prevent damages to the latex model. The dissolving wax and wires were then gently removed from the blood vessel model. The finished MCA aneurysm models can be connected to the CAW via cylindric adapters containing small magnets (N45,

4 x 2 mm) that were attached to the proximal M1 segments. The 3D printed templates and their identical latex-based MCA bi- and trifurcation aneurysm models are presented in **Figure 23**.

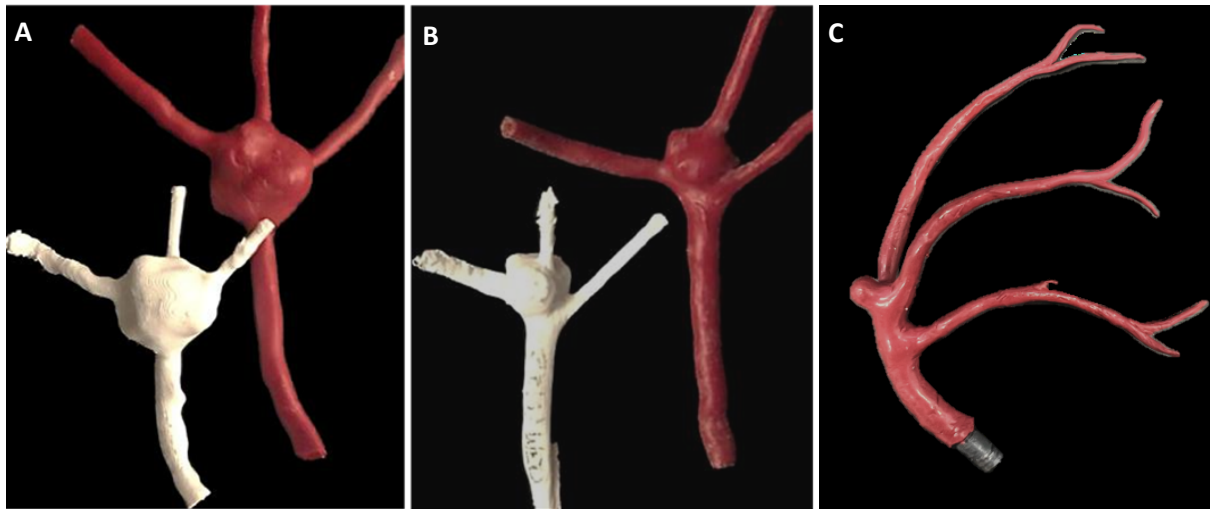


Figure 23: A, B) Latex-based MCA bi- and trifurcation aneurysms samples next to their 3D printed templates C) finished MCA vascular tree with aneurysm located at the MCA bifurcation and early temporal branch (green arrow). A small cylindrical magnetic connector is attached to the proximal M1 segment to facilitate the attachment to the CAW model.

2.2.4 Construction of the meninges

2.2.4.1 Mimicking the arachnoid membrane

The arachnoid membrane is a thin, non-vascular membrane that directly touches the dura mater and is set apart from the pia mater by the subarachnoid space filled with cerebrospinal fluid.^{70,71}

It is distributed unevenly with varying thickness⁷², depending on the complexity of the underlying blood vessels and nerves. While the outer arachnoid membrane surrounds the whole brain, the inner membranes divide the subarachnoid space into cisterns.^{73,74}

The primary objective was to accurately reproduce the tactile and visual characteristics of the arachnoid mater, with particular emphasis on its behavior during the dissection of the Sylvian fissure, where the arachnoid membrane surrounding the Sylvian cistern must be dissected or incised sharply. To mimic the web-like texture of the arachnoid mater, a crystal-clear synthetic resin adhesive (glue) made of polyvinyl acetate (UHU – All Purpose Adhesive, www.uhu.com) was poured onto the palm of one hand. Both hands were then pressed together. By pulling the hands apart transparent strings were created and gently applied to the Sylvian fissure model. By repeating this step five times from different angles, a web-like structure is created. To mimic the tactile properties of the arachnoid membrane, white liquid latex (Lilatex) was diluted with distilled water in a ratio of 3:2 and carefully applied on the glue web using a small brush. Finally, to moisturize the membrane and create a wet natural look and feel, a thin layer of glycerin was applied (**Fig. 24**).

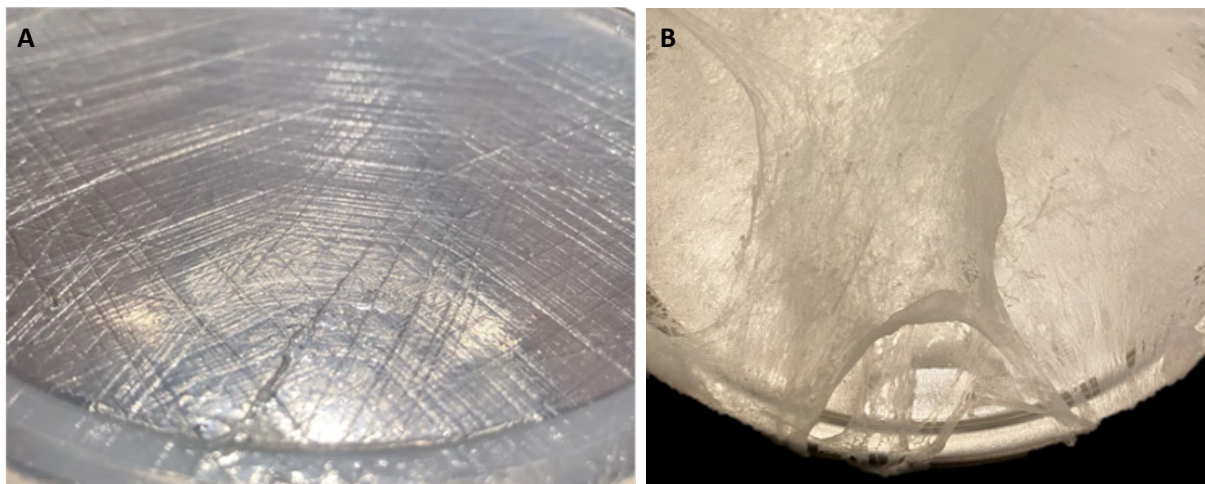


Figure 24: A) Initial web-like base structure of the arachnoid membrane created with transparent polyvinyl acetate strings B) finished arachnoid membrane model.

The employed methodology generates a translucent, reticulated structure resembling the intricate network of the arachnoid membrane and subarachnoid cisterns. The resulting membrane effectively replicates the stabilization of cerebral and vascular structures, which are critical features of the biological arachnoid membrane and pivotal in the microsurgical splitting of the Sylvian fissure (**Fig. 25**).

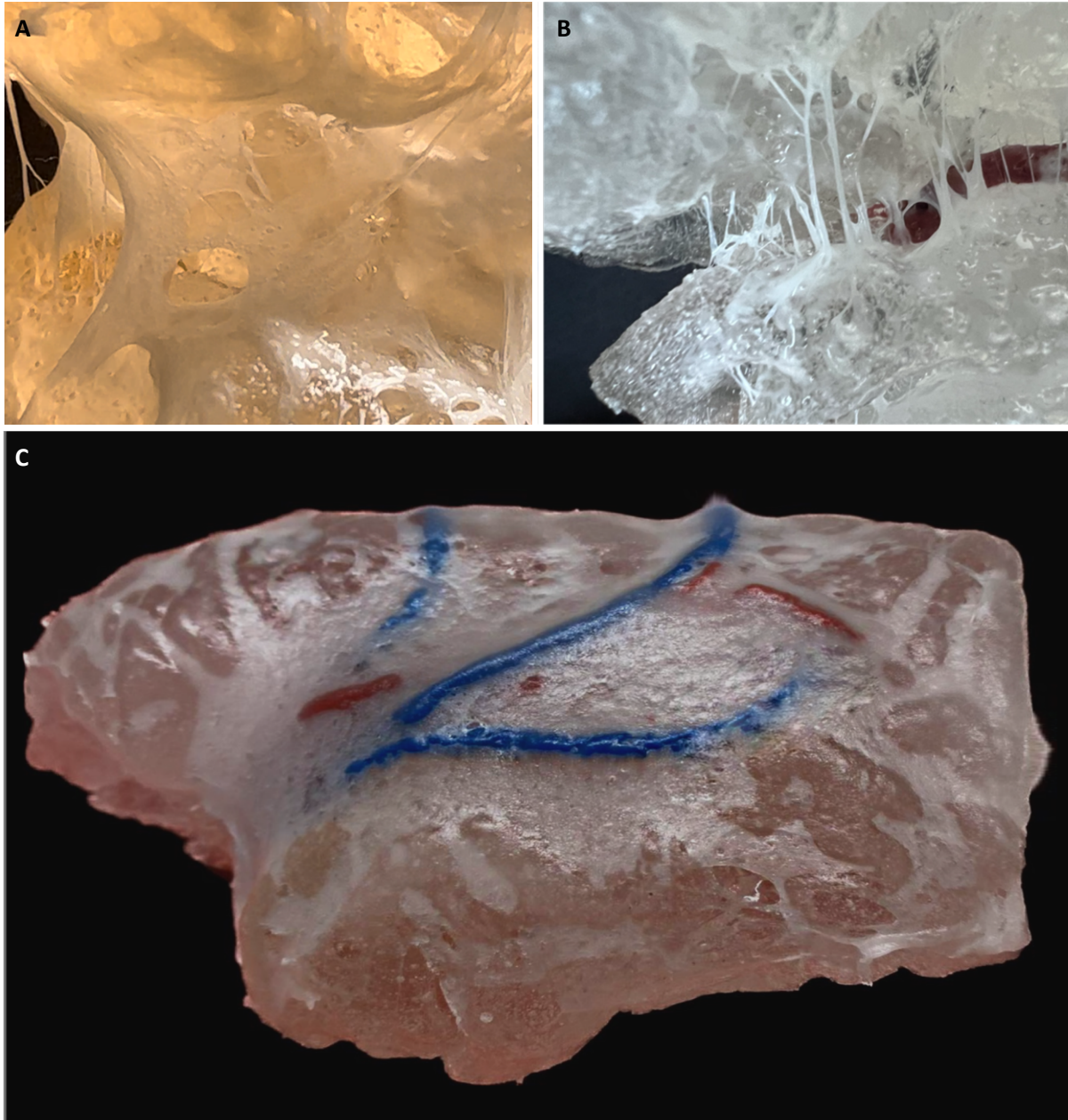


Figure 25: A) Inner subarachnoid spaces consisting of cisterns and major blood vessels B, C) outer arachnoid membrane model applied to the Sylvian fissure with growing thickness around the Sylvian cistern.

2.2.4.2 Mimicking the dura mater

The dura mater must exhibit durability and maintain a specific level of tension. It adheres to the outer surface of the skull bone but should also be detachable and amenable to opening to allow intricate intracerebral microneurosurgical procedures. In connection, ensuring a watertight closure of the dura mater is of paramount importance to prevent cerebrospinal fluid leakage and reduce the risk of subsequent infections.

For a realistic dura replica, a layer of latex was applied to the inner side of the lateral skull base parts. To create a natural look and color, transparent latex by Lilatex was used. For a better adhesion between latex and underground, latex coalescing agent by CREARTEC (ARTIDEE, www.creattec.de) was brushed onto the model's surface before applying the latex. After two minutes of drying in room temperature, a second layer of latex was applied, but this time without the latex coalescing agent to get a thick and dense membrane. The dura model is ready for use after another five minutes of drying in room temperature and maintains its structural integrity for up to eight weeks (**Fig. 26**).

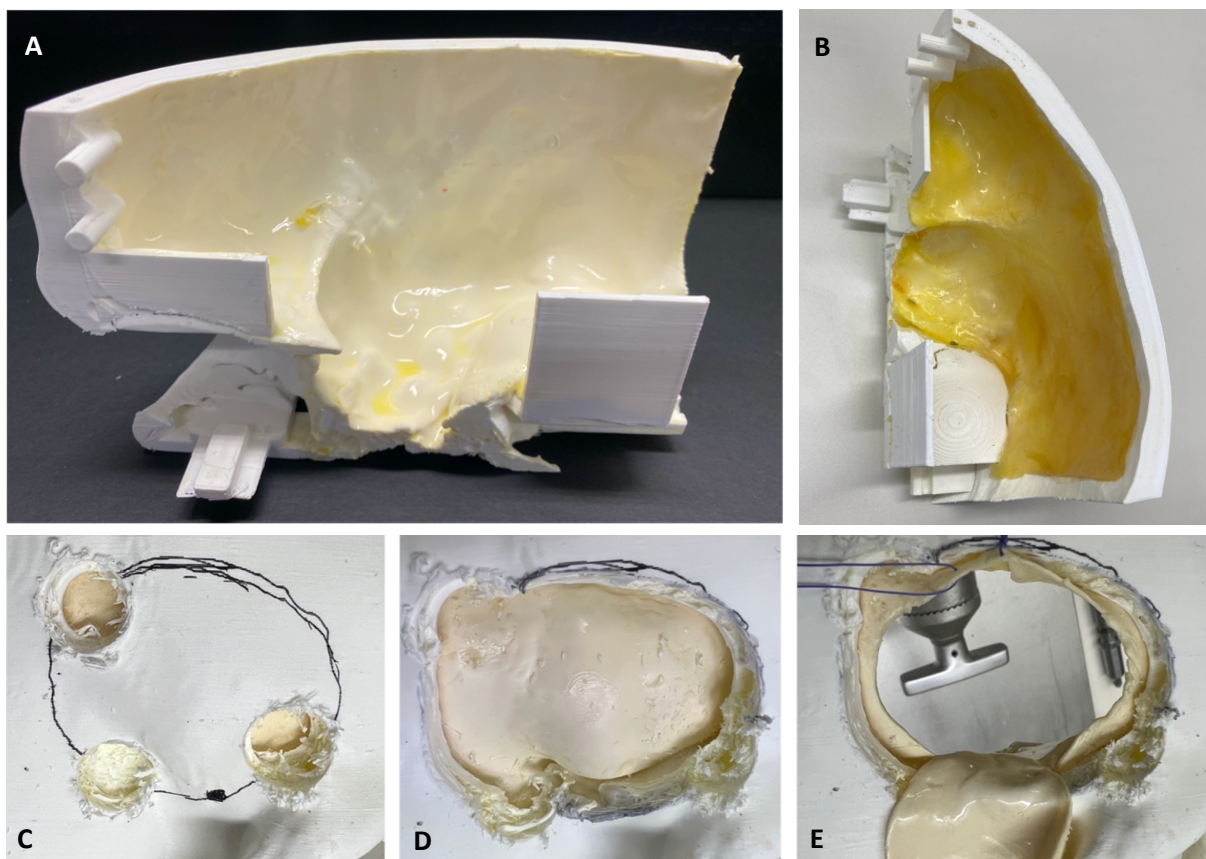


Figure 26: A) Fresh latex-based dura mater model applied to the right cranial base, B) latex-based dura mater model after several weeks maintaining tactile properties and structural integrity C-E) incision and opening of the dura mater.

2.2.5 Simulator assembly

The initial step of the assembly process involves attaching the dura mater to the interchangeable skull base models as delineated in section 2.2.4.2. Concurrently, the middle cerebral artery aneurysm models, and optionally cerebral veins, are carefully placed within the Sylvian fissure models. Before proceeding, the arachnoid membrane layer is applied as described in section 2.2.4.1. Following this, the model of the Sylvian fissure, now containing the MCA aneurysm models, is positioned within the skull base models. The assembly continues with the connection of the skull base models to the central console, which is facilitated by clip mechanisms at the base and frontal parts of the models. During this process, the aneurysm model establishes a magnetic connection with the CAW model placed on the central console. In the final assembly stage, the skull base and central console are securely attached to the remaining calvaria and the occipital region of the head using the integrated plug-in and rail-slide systems. The assembly process of the simulator is depicted in **Figure 27**.

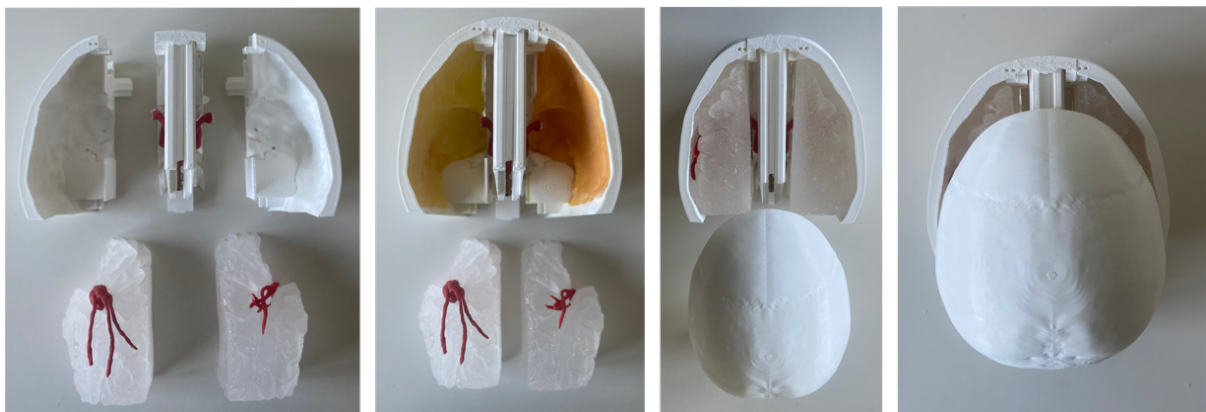


Figure 27: Assembly process of the simulator.

2.3 Study design

2.3.1 Study participants

Three groups of participants (n = 12) with varying levels of neurosurgical experience were recruited for this study (**Table 5**).

- Novice Group (n = 6): 4th- and 5th-year medical students (MS)
- Advanced Group (n = 4): 3rd- and 4th-year neurosurgical residents (NR)
- Expert Group (n = 2): neurosurgeons (NS) specialized in vascular neurosurgery

Table 5: Participants' (n = 12) average age, and experience in neurosurgery.

	Novice Group Medical Students	Advanced Group Neurosurgical Residents	Expert Group Neurological Surgeons
No. of participants	n = 6	n = 4	n = 2
Average age	24 years	29 years	42,6 years
Average experience in neurosurgery	0	3,25 years	12,4 years
Total number of cerebral aneurysm cases (ruptured and unruptured) managed as primary neurosurgeons	0	0	106
Total number of cerebral aneurysm cases assisted in surgery	0	46	~ 280

The novice group included six 4th- and 5th-year medical students previously enrolled in the neurosurgery elective course offered by the Department of Neurosurgery at the University Hospital in Magdeburg.

The advanced group involved four 3rd- and 4th-year neurosurgical residents with basic experience in vascular neurosurgery as assistant neurosurgeons.

The expert group consisted of two attending neurosurgeons with extensive experience in neurovascular surgery.

2.3.2 Simulation setup

The simulations took place inside the microneurosurgical laboratories of the Department of Neurosurgery, where a simulation setup designed to resemble a real-life neurosurgical environment is provided. The centerpiece of the setup is the phantom simulator placed on a table, next to a standard 3-pin head immobilization device. The neurosurgical microscope used for the simulation was a ZEISS OPMI Neuro NC-4, replicating the visual environment encountered in real neurosurgical settings (**Fig. 28**). A full set of neurosurgical instruments including drills, scalpels, forceps, scissors, bone punches, aneurysm clips, and clip appliers were organized on a surgical tray within a hand's reach.

For better comparison and evaluation of the simulator and participants' performances, identical models of MCA with aneurysms located at the MCA-bifurcation were used in all simulations.



Figure 28: A) Simulation setup including a ZEISS OPMI Neuro NC-4 microscope, and microneurosurgical instruments.

2.3.3 Simulation process

The simulation was preceded by an introduction explaining the principles of aneurysm surgery and a presentation about the MCA aneurysm clipping procedure. All study participants regardless of their experience level had to take part in this introduction and were provided with the same basic information. This included a detailed description of the simulated procedure and the relevant anatomical structures with their spatial relationships to the surrounding tissue. Furthermore, the participants were introduced to the simulator and the available instruments and technical devices. All medical students received additional instruction on the operating microscope.

For optimal planning of the head positioning and craniotomy, all participants were able to visualize the 3D reconstructed model of the CAW, including the MCA branches and selected aneurysm size, angulation, and morphology, on a portable tablet PC (iPad Pro 10.5, www.apple.com). The simulation started with the positioning of the head in a 3-pin head immobilization device (MAYFIELD®). The surgical approach was predefined to the standard pterional approach.⁷⁵ Craniotomy and dural incision

were performed using a craniotomy drill and mill (**Fig. 29**). To expose the aneurysm, participants were asked to dissect the arachnoid mater and open the Sylvian fissure under the microscope. After splitting the fissure and identifying important landmarks and exposing the aneurysm, proximal control had to be ensured before a clip was chosen to be placed on the neck of the aneurysm. Each participant performed the procedure four times: twice, on each side of the simulator, after receiving the introduction and again after a period of three to five days. Per attempt, each participant was given one chance to clip the aneurysm (**Fig. 30**).

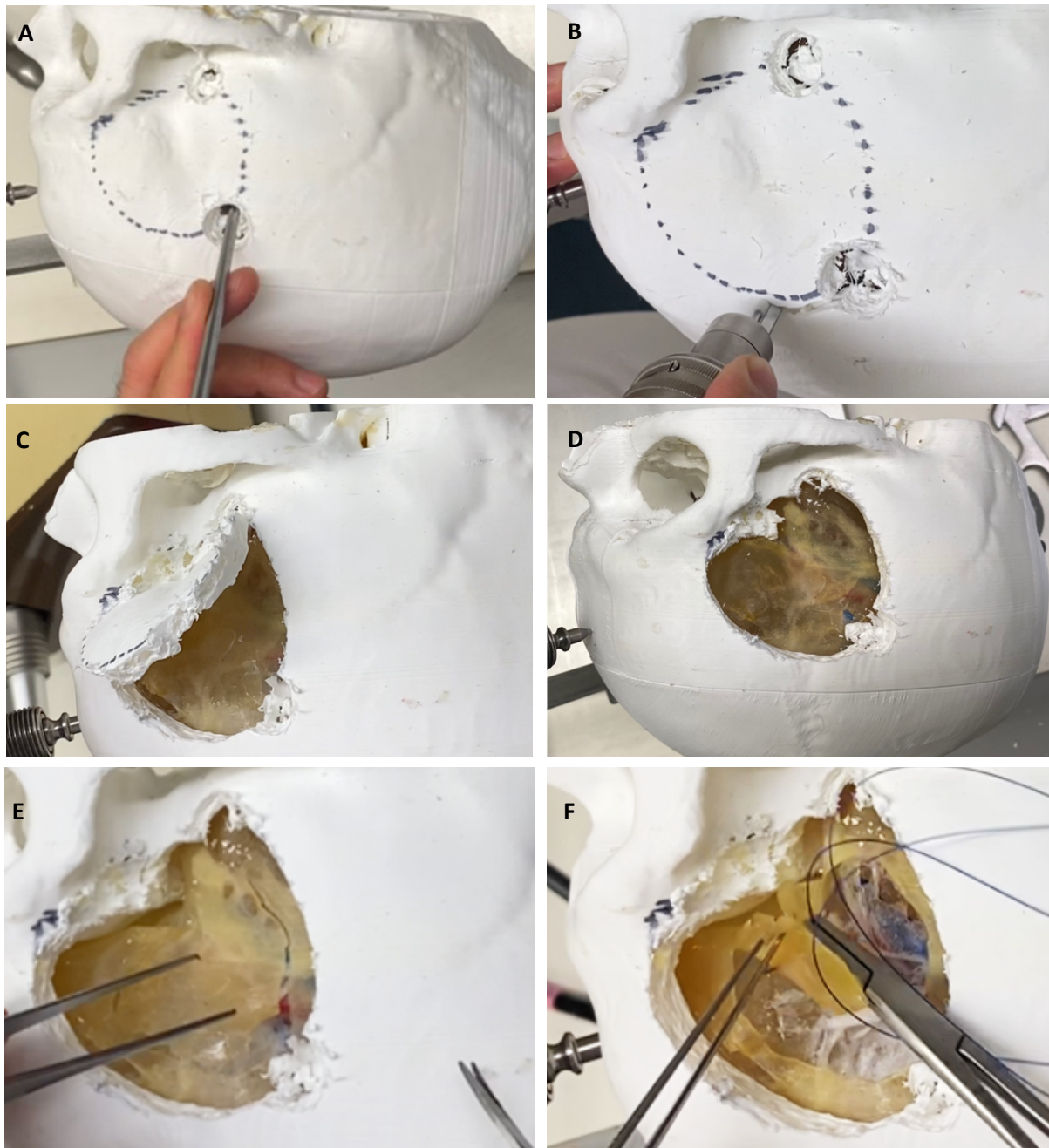


Figure 29: Simulation process starting with A) the positioning and fixation of the head in a three-point fixation device B) planning of the pterional craniotomy, burr hole placement, removal of splinters with a bone punch C, D) craniotomy placement, and removal of bone flap E, F) dural incision and opening.

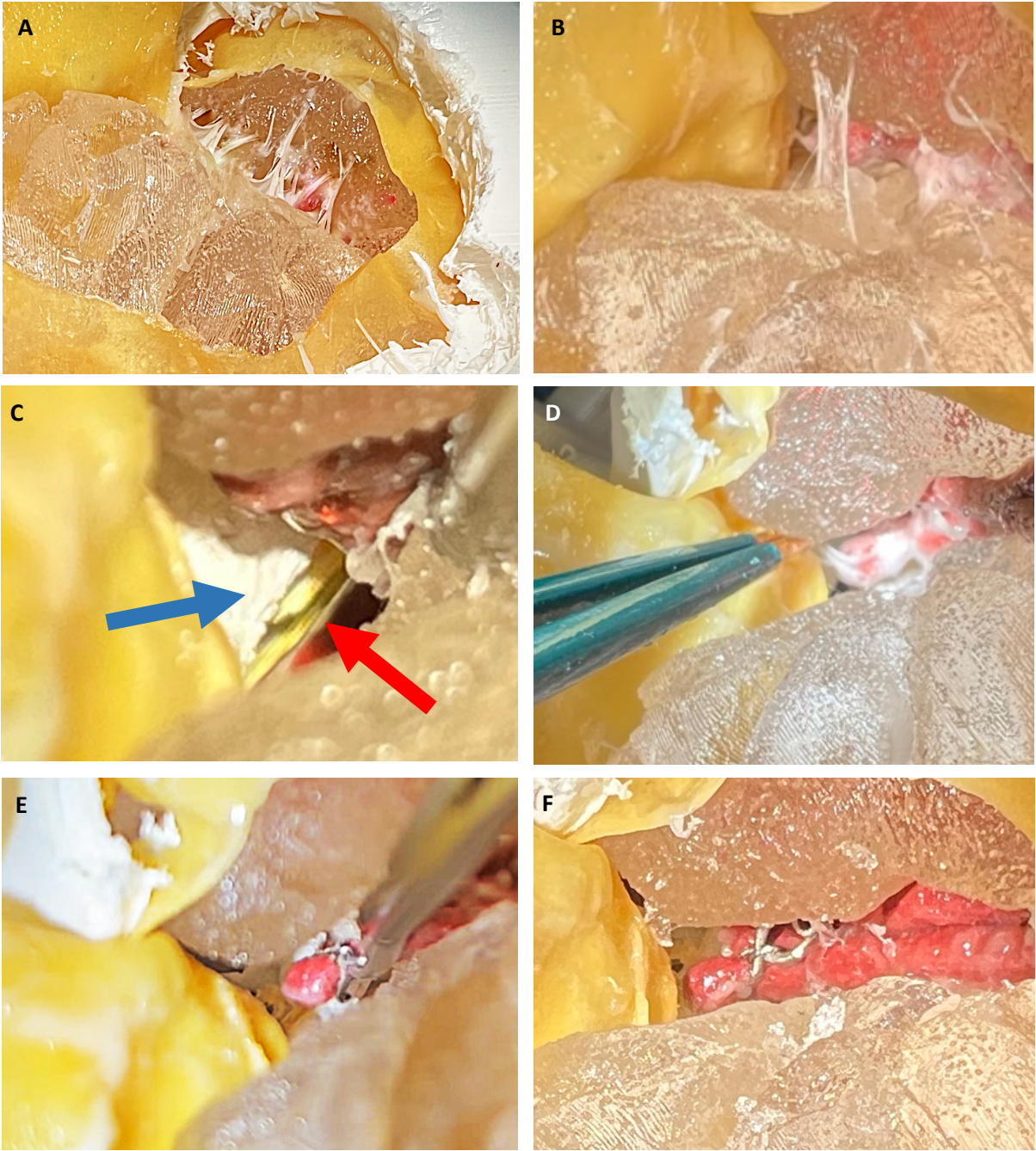


Figure 30: A, B) Microsurgical dissection of arachnoid membrane and opening of the Sylvian fissure C, D) Identifying the anterior clinoid process (blue arrow) and optic nerve (red arrow), visualization of aneurysm, preparation of aneurysm for good neck exposure E, F) successful clipping of a right MCA bifurcation aneurysm.

2.3.4 Quality assessment

The evaluation of the simulator was grounded in both subjective and objective validation techniques⁷⁶ **(Fig. 31)**. Face and content validity serve as subjective measurements, predominantly assessed through questionnaires and surveys. Specifically, face validity pertains to the extent to which a simulator emulates real-life situations in terms of appearance and functionality.

Content validity pertains to the simulator's comprehensiveness in covering the relevant surgical skills, techniques, and procedures that a trainee needs to learn. It assesses the model's effectiveness during a specific skill training to improve participants' techniques.

Construct validity is an objective validation method and refers to the simulator's ability to distinguish between different levels of skill and expertise of trainees based on their performance, providing assessment of progress and areas for improvement.

Predictive validity evaluates the simulator's ability to predict a trainee's performance in real-life surgical situations. A simulator with high predictive validity can reliably forecast how well a trainee will perform during actual surgery, based on their performance during simulation training.

However, for the predictive validity to be assessed accurately, post-training performance of the participants in real surgical scenarios would need to be evaluated to see if improvements on the simulator translate to real-world skill enhancements.

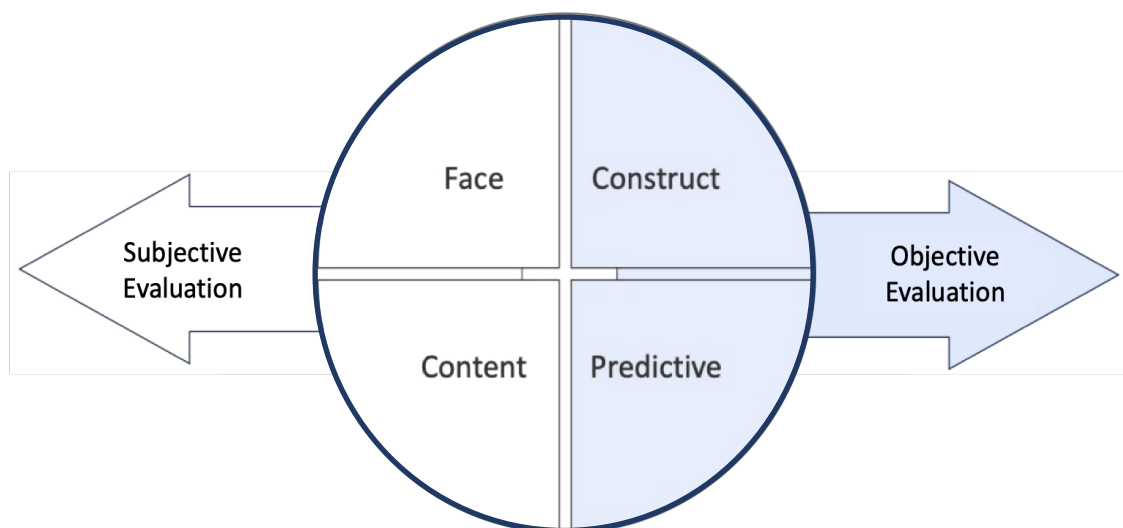


Figure 31: Main types of research validity based on objective and subjective assessments.

The simulation was directly followed by a survey for the assessment of face and content validity of the simulation. The participants were asked to gauge their attitude towards the simulator, the educational usefulness of the simulation, as well as its perceived accuracy and scored on a 5-point Likert scale (**Tab. 6**). All study participants were observed during the simulations and assessed by two experienced neurosurgeons based on a modified version of the Objective Structured Assessment of Aneurysm Clipping Skills (OSAACS)^{77,78} tool. (**Tab. 7**). OSAACS, which is based on the Objective Structured Assessment of Technical Skills (OSATS)⁷⁹ tool, specifically rates surgical clipping skills based on participants' performances during surgery or simulation to rate technical skills and measure progress in training over time. The tool was slightly modified to include all relevant steps of the procedure that are included in the simulation.

Table 6: Subjective evaluation and assessment questionnaire completed by each participant via the open source on-line statistical survey web app LimeSurvey.

LimeSurvey

Aneurysm Clipping Simulator Participant Survey

There are 18 questions in this survey.

Participant Information

Year of Birth

Gender

Female Male No answer

*Skill level

Novice (Medical Student)

Advanced (Resident)

Expert (Neurosurgeon)

Other:

*Years of experience / Academic years (student) / Years in residency (resident)

1 5

2 6

3 Other:

4

*Number of cerebral aneurysm cases assisted in surgery (ruptured and unruptured)

assistance

*Number of cerebral aneurysms clipped or treated as primary surgeon (ruptured or unruptured)

primary surgeon

LimeSurvey

Aneurysm Clipping Simulator Participant Survey

There are 18 questions in this survey.

Simulation Assessment: Physical Model

* Attitude towards Simulator

	Strongly Disagree	Disagree	Indifferent	Agree	Strongly Agree
This or similar simulators will improve procedure training	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Simulators should be used more extensively in surgical training	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel like I can train dexterity with this simulator	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel successful in accomplishing the task.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The simulator is easy to handle	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* Educational Usefulness

	Strongly Disagree	Disagree	Indifferent	Agree	Strongly Agree
The simulator is appropriate to teach the procedure.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The simulator is easy enough to use for educational purposes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Practice on this model can help to improve the microsdissection technique	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Practice on this model can help to improve skills in handling clip appliers and aneurysm clipping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Practice on this model will improve surgical technique when applied to patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would use the simulator for surgical training.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Practice on this model will improve surgical technique when applied to patients	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

LimeSurvey

* Perceived Accuracy

	Strongly Disagree	Disagree	Indifferent	Agree	Strongly Agree
Anatomical landmarks are easily identifiable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The drilling of the bone feels realistic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The brain tissue feels realistic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The tactile feedback of the brain while opening the sylvian fissure feels realistic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The task is easier compared with real surgery.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The task is more difficult compared with real surgery.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The task is comparable to real aneurysm surgery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The model replicates actual brain aneurysm surgery.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* Tactile Realism

	Strongly Disagree	Disagree	Indifferent	Agree	Strongly Agree
The drilling of the bone feels realistic.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The brain tissue feels realistic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The tactile feedback of the brain while opening the sylvian fissure feels realistic.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The model helps to get a feeling for tactile properties of tissue and aneurysm.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

LimeSurvey

* Anatomical understanding

	Strongly Disagree	Disagree	Indifferent	Agree	Strongly Agree
Anatomical landmarks are easily identifiable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The model helps in understanding the aneurysm configuration.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The simulation helps in understanding the spatial relationships between anatomical structures.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The model helps in understanding spatial relationships in the sylvian fissure.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The simulator helps in understanding the microscopic view and surgical field.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The simulation helps in understanding the surgical approach.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* Technical Skills Improvement

	Strongly Disagree	Disagree	Indifferent	Agree	Strongly Agree
Training with the simulation improves surgical skills.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel like I can train dexterity with this simulator.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Practice on this model can help to improve microsdissection technique.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Practice on this model can help to improve skills in handling clip appliers and aneurysm clipping.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Training with the simulator improves respect for tissue during surgical preparation.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Training with the simulator helps in improving the time-flow of operation and forward planning.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Training with the simulator helps in preparing for real surgery.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The model is useful for planning and performing the correct craniotomy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The model helps with choosing the best clip for the aneurysm configuration.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Table 7: Modified version of the Objective Structured Assessment of Aneurysm Clipping Skills (OSAACS).

	1	2	3	4	5	Attempt 1	Attempt 2	Attempt 3	Attempt 4
OPERATOR POSITIONING AND POSTURE	Hunched back, twisted wrists, shrugged shoulders, wide range of movements		Good posture and positioning at first but deteriorates by the end of procedure, rarely makes wide-range movements		Optimally ergonomic and relaxed posture, economy of movements				
USE OF THE SURGICAL MICROSCOPE	Readjusts positioning, focus, and working distance frequently, frequently out of focus or using a magnification level that impedes proper field navigation		Focused most of the time but readjusts at multiple instances, familiar with the use of microscope but not yet proficient		Optimizes zoom, focus, and optical settings at the beginning of task and adjusts only when needed				
INSTRUMENT KNOWLEDGE AND HANDLING	Repetitively uses the wrong instrument for task Repeatedly makes tentative or awkward moves with instruments		Uses the correct instrument for task most of the time, quickly switches to the correct instrument after a mistake. Competent use of instruments. Occasionally appears stiff and awkward		Perfect matching of instruments and tasks at hand, knows the instruments well, and chooses according to surgical need. Fluid moves with instruments				
MOTION, TIME FLOW AND FORWARD PLANNING OF OPERATION	Many unnecessary moves Frequently stops operating or needs to discuss next move		Efficient time and motion, but some unnecessary moves Demonstrates ability for forward planning with steady progression of operative procedure		Economy of movement and maximum efficiency Obviously planned course of operation, with effortless flow from one move to the next				
RESPECT FOR TISSUE	Often used unnecessary force on tissue or caused damage by inappropriate use of instruments		Careful handling of tissue but occasionally caused inadvertent damage		Consistently handled tissue appropriately with minimal damage				
HEAD POSITIONING	Head is positioned on the wrong side, readjusts repeatedly, Mayfield pins cause damage to tissue, head is not sufficiently secured		Demonstrates ability to position head inside Mayfield clamp. Head is fixed securely; head position is appropriate for the pterional craniotomy.		Flawless positioning and fixation of the head inside Mayfield clamp				
CRANIOTOMY PLANNING AND PLACEMENT	Craniotomy is planned and executed wrongly or is either too big or too small.		Moderately good craniotomy technique. The craniotomy is sufficient for the procedure.		Excellent technique of planning and performing the craniotomy based on the individual pathology and desired surgical approach				
QUALITY OF ANEURYSM CLIPPING	Poor technique, parent vessel compromise, or insufficient clipping		Moderately good technique, parent vessel is patent or slightly stenosed, complete exclusion of aneurysm		Excellent technique, optimal clip position, aneurysm excluded from flow, no parent artery compromise				
QUALITY OF DISSECTION	Poor technique, frequent damage of vessels, insufficient aneurysm exposure		Moderately good technique of dissection in proximity to vessels with acceptable or occasional accidental damage that does not affect structural integrity of the vessel, adequate exposure of aneurysm and parent vessels		Excellent technique of sharp and blind dissection, uninjured vessels, adequate and sufficient exposure of the aneurysm and parent vessels				
Participant: # _____						/45	/45	/45	/45

2.3.5 Statistical analysis

The survey was designed and conducted via LimeSurvey 6.1.8 (www.limesurvey.org, GNU General Public License,), an open source online statistical survey web app, which also provided the statistical analysis of the ordinal data. Access to the tool was provided through the data center of the Otto-von-Guericke University (www.limesurvey.ovgu.de).

Structured analysis of the participants' surgical skills performances was assessed by two independent neurosurgeons based on the OSAACS tool. Statistical analysis of the data was performed with SPSS version 28.0 (Statistical Package for the Social Sciences, SPSS Inc. IBM).

3. Results

3.1 Efficacy of simulation

3.1.1 Face and content validity

The results from the 5-point Likert-scale questionnaire on participants' attitudes towards the simulator and its educational usefulness are summarized in **Figures 32 and 33**:

All participants (n = 12, group 1-3) unanimously agreed that the simulator is easy to use, indicating a very positive perception of its user-friendliness. 91.6% of the participants, strongly agreed, and 1 participant (8.3%) agreed that the simulator is helpful in training dexterity, suggesting high confidence of participants in the simulator's ability to improve manual skills. 9 participants (75%) strongly agreed, and 3 participants agreed that they felt successful in accomplishing the task, indicating that the simulator effectively conveyed a sense of achievement. All 12 participants (100%) strongly agreed that simulators should be used more extensively in surgical training, showing unanimous support for the broader adoption of this technology. All 12 participants (100%) strongly agreed that this or similar simulators will accelerate the development and improvement of surgical skills, emphasizing their belief in the positive impact of simulator-based training.

All participants (100%) strongly agreed that this or similar simulators will improve procedure training, further endorsing the benefits of simulation in surgical education.

All participants (100%) strongly agreed that this or similar simulators will accelerate their learning curve as a student/resident, highlighting the potential for simulators to facilitate faster skill acquisition. Most participants (91.6%) strongly agreed that the simulator is appropriate to teach the procedure and helpful in improving microdissection techniques and clipping skills.

Participating residents and neurosurgeons (group 2 and 3, n = 6) further rated the simulator's visual, tactile, and anatomical accuracies (**Figures 34**).

According to them, the model replicates actual brain aneurysm surgery (83.3% strongly agree, 16.6% agree). In direct comparison to real surgery, 50% of participants perceived the task as being easier, while none of them perceive it as being more difficult. The drilling of the bone and the tactile feedback of the brain while opening the Sylvian fissure were deemed realistic by most participants (83.3% strongly agree, 16.6% agree).

The accuracy of the brain replication also influenced the face validity of the model, which was shown by the satisfaction of participants with the haptic realism of the simulation. Realism of the brain tissue was rated highly by the participants (83.3% strongly agree, 16.3% agree).

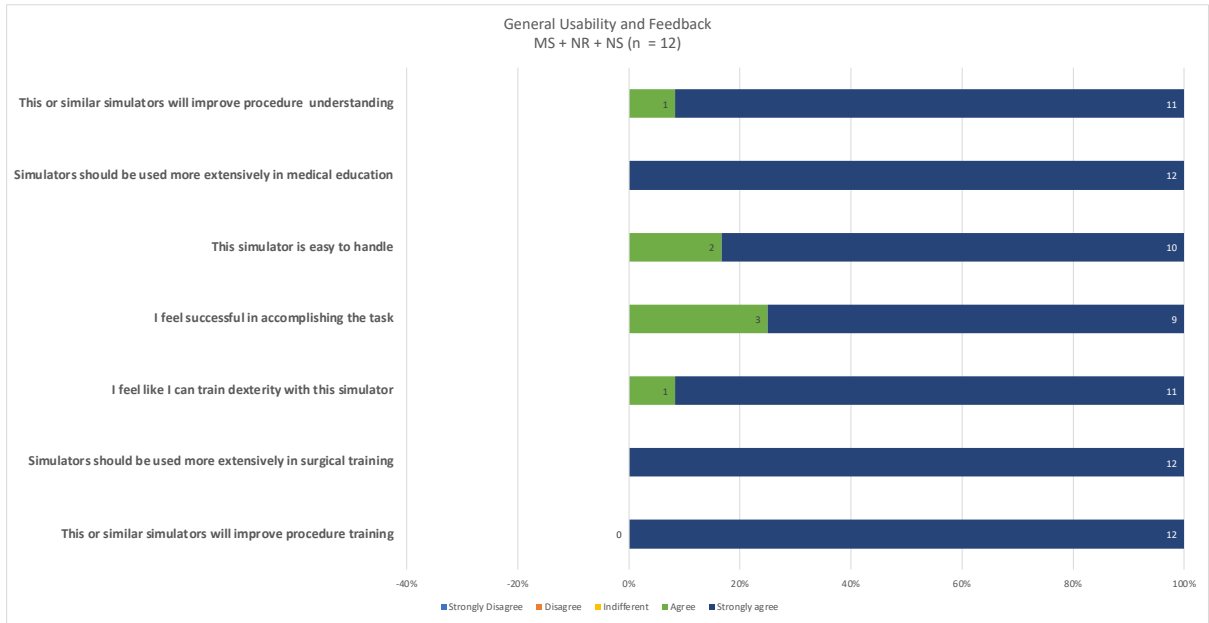


Figure 32: Participants' responses (group 1-3, n = 12) to survey questions on the simulator's general usability derived from a 5-point Likert scale.

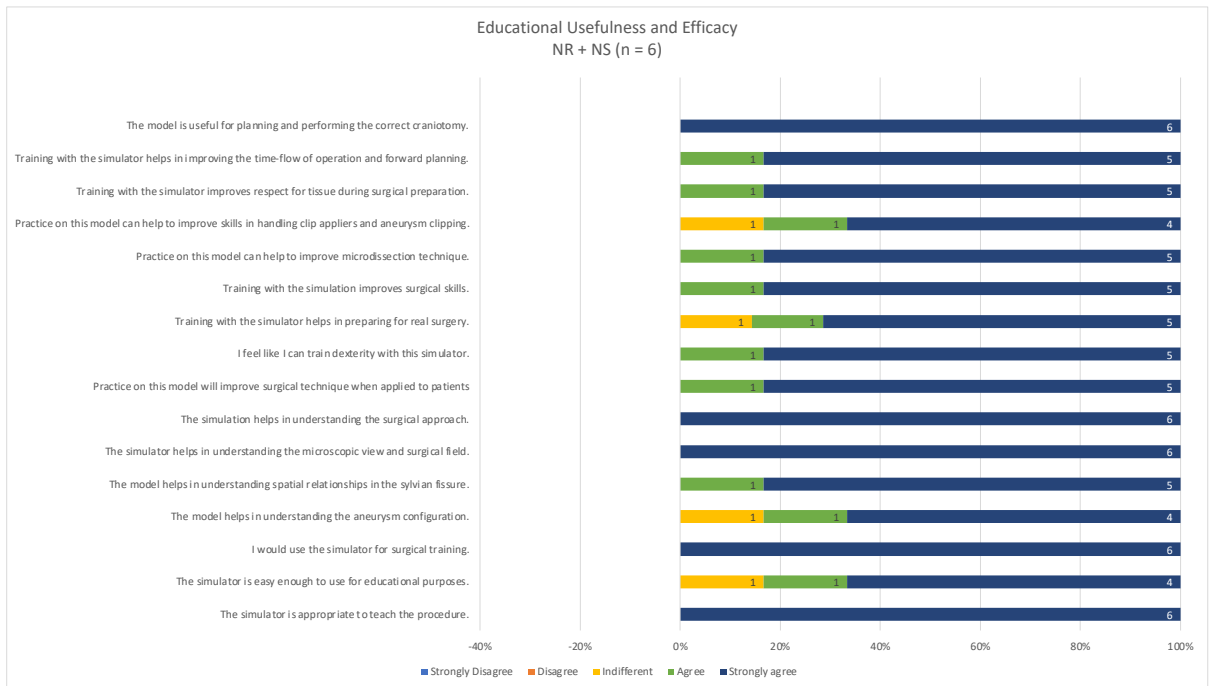


Figure 33: Average responses of participating neurosurgical residents and neurosurgeons (group 2 + 3, n = 6) on the simulator's educational usefulness derived from a 5-point Likert scale.

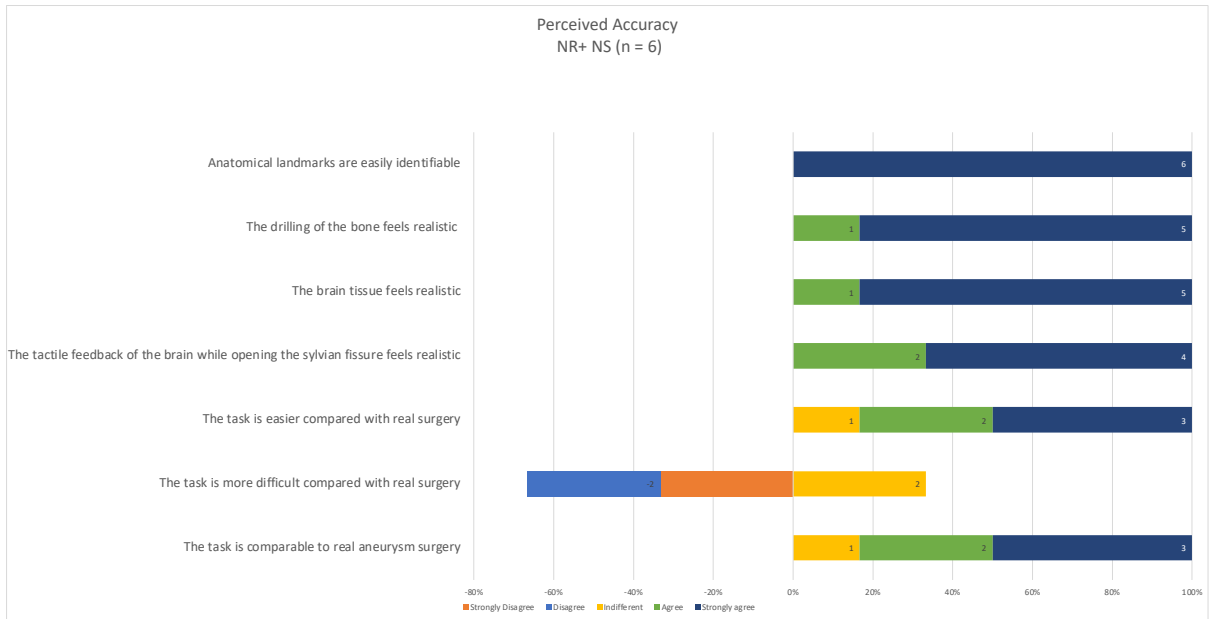


Figure 34: Average responses of participating neurosurgical residents and neurosurgeons (group 2 + 3, n = 6) on the simulator’s realism and their perceived anatomical and tactile accuracies derived from a 5-point Likert scale.

3.1.2 Construct validity

Mean scores of the objective assessment of technical skills based on OSAACS among the novice group (MS, n = 6), the advanced group (NR, n= 4) and the expert group (NS, n=2) on their first attempts demonstrating a high construct validity of the model as it realistically reflects the different levels of expertise and technical skills in each group (Fig. 35).

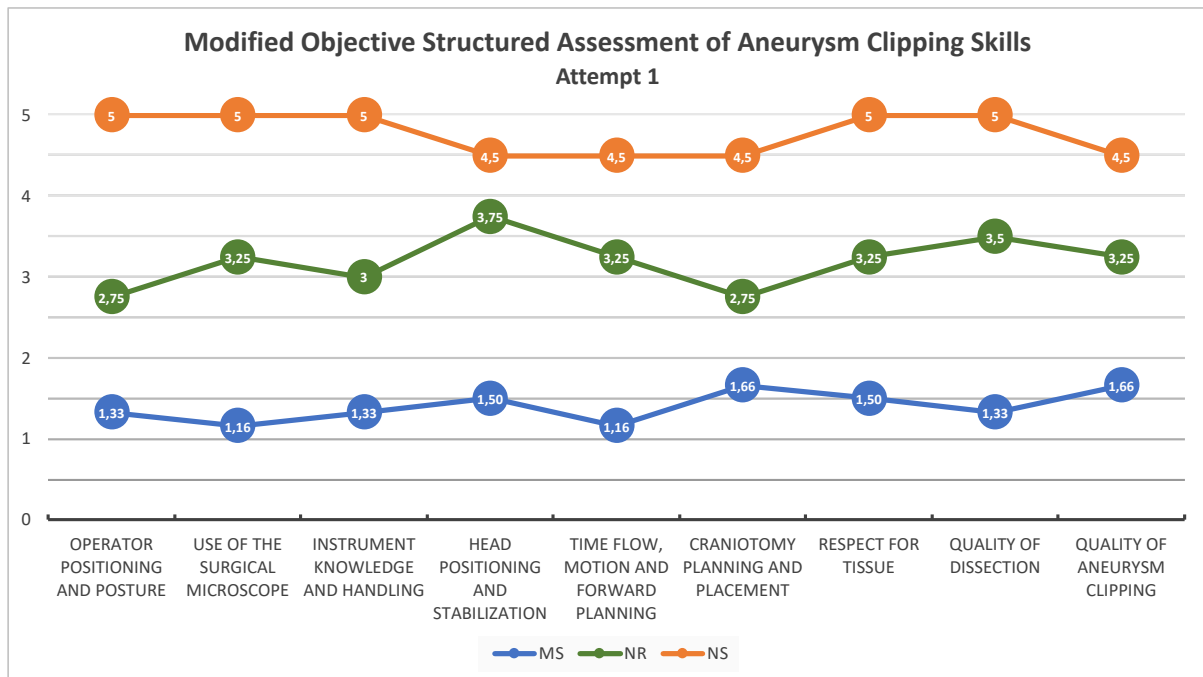


Figure 35: Results of the objective assessment of technical skills in aneurysm clipping. The average scores of the expert, advanced and novice groups’ first attempts on the simulator reveal a high construct validity of the simulator as it realistically discriminates and reflects the different levels of experience and technical skills of each group.

The most significant improvements could be observed in the novice group, which experienced a rapid and considerable increase in accuracy, timing, and quality as assessed by experienced neurosurgeons. Over the course of four attempts, the novice students' abilities to perform even the most critical aspects of the procedure improved substantially, in some areas even comparable to expert level skills, underlining the efficacy of the simulator to convey microsurgical understanding and techniques. (Figure 36). The experts (NS) generally exhibited high performances from the start, which did not significantly improve over time, indicating that the simulator is correctly identifying the already developed skills of experienced neurosurgeons



Figure 36: Objective assessment of technical skills of participating medicals students (MS), neurosurgical residents (NR) and neurosurgeons (NS) over a course of four attempts in critical areas of the procedure over the course of four attempts showcasing a rapid and significant improvement in surgical skills among medical students and young resident.

An overview of the results of the objective assessment of participating medical students (n = 6), neurosurgical residents (n = 4) and neurosurgeons (n = 2) in each category of the modified OSAACS, as assessed by two independent neurosurgeons during all four attempts, are presented in **Figure 37**.



Figure 37: Overview of the objective assessment of technical skills of participating medical students (MS), neurosurgical residents (NR) and neurosurgeons (NS) over a course of four attempts revealing a rapid and significant acceleration in surgical precision and quality among novice medical students and inexperienced residents.

3.2 Cost analysis

The costs are divided into material costs, first-time fabrication costs, and cost per simulation. This cost analysis does not include the purchase price of a 3D printer as it varies greatly depending on the model and type. However, most commercially available desktop 3D printers are sufficient for the construction of this simulator. Due to its design, the simulator only requires the skull base and meninges to be periodically replaced after each simulation, which significantly lowers the operating expenses of the simulator. Due to the materials employed, the remainder of the skull model as well as the models of the Sylvian fissure and cerebral vessels are highly durable and do not necessitate renewal when used appropriately. The largest portion of the cost, excluding the acquisition of the 3D printer, is attributed to the silicone used for the one-time creation of negative molds for casting the candle gel-based models of the Sylvian fissures. The bony structures are produced using standard PLA filaments, while the brain model is fabricated using commercial candle gel, and the vessels and meninges are made with latex. These materials are cost-effective compared to other alternatives, such as polyacrylamide or agar. Since at least two simulations can be performed with each set (pterial approach on each side), the cost for a single clipping simulation is approximately € 4,40. The materials used for the first-time fabrication and continued usage of this simulator are summarized in **Table 8**.

Table 8: First-time production cost and continued operating expenses of the simulator.

Material	Type	Amount	Manufacturer	Material costs	First time fabrication	Cost per simulation
Magnets	N45 - round- 4 x 2 mm	20 pcs	Supermagnete	4,20 €	4,00 €	0,00 €
Latex coalisartor	Liquid	100 ml	ARTIDEE	5,00 €	2,00 €	0,80 €
Adhesive	Transparent - 125g	125 g	UHU	7,00 €	2,00 €	0,50 €
Silicone release agent	Vaseline	50 ml	TFC Troll Factory	10,00 €	2,00 €	0,00 €
Candle gel	Colorless	750g	Rayher	12,00 €	8,00 €	0,00 €
Latex	Liquid - red	1 L	Lilatex	12,90 €	3,00 €	0,00 €
Paraffin wax	Colorless –	1 kg	Materialix	13,90 €	1,50 €	0,00 €
Latex	Viscous - white	1 L	Lilatex	15,00 €	4,00 €	1,20 €
3D filaments	PLA - 1,75 mm - white	1 Kg	PimaValue	19,00 €	12,00 €	1,90 €
Moulding frame	200 x 200 mm	1 pc	TFC Troll Factory	24,00 €	24,00 €	0,00 €
Silicone	22-Shore A	2 L	Wagnersil Dental	87,00 €	87,00 €	0,00 €
Total project costs				210,00 €	149,50 €	4,40 €

4. Discussion

This study provides a blueprint for the construction and evaluation of a novel, practical, cost-effective simulator as an educational and training tool for the surgical management of middle cerebral artery aneurysms. The continuous decline in surgical caseload, particularly in the field of vascular neurosurgery due to the rise of endovascular treatment options, and further aggravated by work-hour-regulations, poses an existential challenge to the existing neurosurgical training model, which heavily relies on gained experience thorough practice and repetition in the operating room. Despite the rise of endovascular treatment options, the microsurgical management of cerebral aneurysm often remains the superior approach, particularly for middle cerebral artery aneurysms, underscoring the importance for alternative training methods for young neurosurgeons to develop and maintain their surgical skills through focused, repetitive, and risk-free practice. The presented methodology involves the development and evaluation of the simulator using high-detailed 3D reconstruction and post-processing techniques, additive manufacturing technologies, extensive material research and crafting aiming to provide a realistic surgical experience that is transferable to real-life settings. Participants across varying levels of neurosurgical experience were recruited to test and evaluate the simulator using a microneurosurgical microscope and instruments. Experienced neurosurgeons deemed the simulator as highly effective and realistic in simulating the key steps of the procedure and mimicking tactile properties of the living brain and meninges. Objective assessment of the participants' performances revealed high educational usefulness and demonstrated a rapid improvement in surgical abilities, particularly among novice medical students and neurosurgical residents. Following the provided blueprint, the simulator can be reconstructed and built in a timely manner without extensive investments or technical expertise, facilitating its integration into the neurosurgical curriculum as an effective surgical training tool.

4.1 Interpretation

The question of how to develop genuine expertise in highly competitive fields such as sports, music, or surgery has long been a focus of interest and research. According to the „deliberate practice“ theory, based on the 1993 study by Ericsson et al.⁸⁰⁻⁸², developing real expertise requires considerable, focused, and sustained efforts, particularly on task one cannot perform perfectly. A study conducted by Bradley and Bligh in the year 1999 demonstrated that skills learned by first year medical students in a skills lab were retained if students were given the opportunity to perform deliberate practice.⁸³

In the high-risk high-stakes field of neurosurgery, however, the deliberate practice approach of procedures one cannot perform perfectly cannot be applied without hesitation and concern for patient safety.

As traditional neurosurgical training methods fail to provide aspiring neurosurgeons with the exposure needed to gain experience and hone their skills, the desire for alternative training methods that allow deliberate, effective alternative training opportunities has grown immensely.

Physical synthetic simulators have the potential to overcome the limitations of cadaveric and screen-based simulations by providing pathology-specific, reproducible, and tactilely accurate hands-on training opportunities in a safe environment.

The underlying premise of simulation-based training, is that abilities developed within simulated environments are seamlessly transferable to real-world scenarios.^{84,85}

However, the synthetic simulators for cerebral aneurysm clipping that have been introduced so far, vary heavily in design structure, anatomical and tactile accuracy, production complexity and acquisition cost. Some simulators mainly focus on the visualization of the aneurysm configuration for surgical planning and therefore print or cast aneurysm models without the surrounding anatomical structures.^{86,87} For a better understanding of spatial relationships in the surgical cavity, some developers reconstruct a skull model for craniotomy without a model of the brain, which is used for pre-operative planning of aneurysms in challenging locations.⁸⁸⁻⁹⁰ Liu et al. designed a simulator using perfused blood vessel models with blister-like aneurysm bulging and different wall thicknesses.⁹¹ While the fragile aneurysm model allows for effective training of dexterity and fine motor skills, the manufacturing process of the model does not allow patient-specific replicas and the simple silicone brain model limits the haptic experience of the simulation.^{52,92}

Recently, there has been a surge in the popularity of commercially accessible phantom simulators designed for cerebral aneurysm clipping, offering a solution to the diminishing surgical caseload. However, the available products not only come with high acquisition cost and limited reusability, but also fall short in adequately replicating the key aspects of the clipping procedure^{93,94} such as head positioning and placement, craniotomy planning and execution, opening of the dura mater, and dissection of the arachnoid membrane, essential for effective surgical simulation training.

The goal of this study was to overcome existing barriers in implementing simulation training into a neurosurgical curriculum by developing a highly realistic yet cost-effective and easily reproducible simulator.

To achieve this goal and meet the prerequisites delineated in the introduction of this study, the development and evaluation of the simulator was grounded on two critical aspects:

- 1: is the simulator realistic enough to be used as a surgical training tool?
- 2: if so, how efficient is the simulator as a surgical training tool?

The question whether a simulator is realistic enough should be answered prior to the evaluation of the simulator's efficacy since only a realistic simulation can improve performance in real-life scenarios and therefore be deemed effective. Concurrently, a lack of realism will not only limit the amount of progress but may negatively affect intraoperative performance and endanger patients' lives.

Development of the simulator

The focus during the simulator's construction lied in the life-like simulation of the key steps of the clipping procedure, which required the diligent recreation of the correct anatomy and tactile properties of the brain and surrounding structures as encountered in real-life settings.

The construction of the Sylvian fissure, which houses critical neurovascular structures that demand precise and delicate surgical manipulation, involved the meticulous anatomical reconstruction, material research, rheological testings and the expertise of seasoned neurosurgeons to accurately recreate the tactile properties of the living brain. The result is an anatomically and haptically realistic, easily reproducible, and inexpensive model of the Sylvian fissure than can be used for simulation training of a variety of surgical procedures and techniques. The model permits the accurate incorporation of the vascular model within the lateral sulcus and enables the microsurgical dissection of the arachnoid membrane and the Sylvian fissure contingent upon the location and morphology of the selected MCA aneurysm.

The incorporation of accurate tactile and rheological properties of the brain and skull enables trainees to develop a keen sense of touch, dexterity, and instrument handling that can be transferred to any neurosurgical procedures involving the use of microsurgical instruments and a microscope.

A major advantage of the model lies in its design and reusability. The exchangeable parts of the skull allow a faster replication of the model while reducing material costs.

By employing freeware and readily available materials, the presented simulator can be reconstructed and built in a timely manner without extensive investments or dependency on software engineers, facilitating its integration into neurosurgical programs. The CAW complex can be modified to allow the connection of a pulsatile pump to simulate blood flow, allowing a pulse synchronous clipping simulation including complications encountered during surgery such as aneurysm rupture. The

simulator's capacities can be expanded by adding pathologies such as gliomas or metastases to the Sylvian fissure model as well as by adjusting material concentrations to simulate scenarios such as an "angry brain".

Evaluation of the simulator

The presented methodology focused on the accurate recreation and simulation of the most important step in the aneurysm clipping procedure with the goal to avoid negative learning habits and negative transfer. To create an immersive experience, a neurosurgical operating room including all necessary instruments and equipment used in real-life aneurysm clipping scenarios was provided.

Starting from the correct head positioning and stabilization, through the correct craniotomy planning and placement to the microsurgical dissection of the Sylvian fissure and correct application of the clip, every key step of the procedure can be simulated to improve confidence in the operating room.

After opening the skull and dura mater, the Sylvian fissure can be explored by dissecting the arachnoid membrane and subarachnoid cisterns. Under the microscope, the three-dimensional relationships between the aneurysm and other anatomic structures, such as cranial nerves, arteries, and veins can be explored and visualized to train spatial awareness and hand-eye coordination. After exposing and preparing the targeted aneurysm and its neck, the clipping can be performed using real neurosurgical instruments and clips.

Subjective evaluation: The participants' responses to the survey revealed overwhelmingly positive attitudes towards the simulator, with strong agreement on its ease of use, effectiveness in training dexterity, and potential to accelerate the surgical learning curve. The experienced participants overwhelmingly rated the simulation as highly realistic and comparable to real surgery.

The medical students and young residents highlighted the relevance of steps like head placement in the Mayfield clamp and craniotomy as they are crucial for the surgical approach and understanding anatomical and spatial relationships depending on the aneurysm size, location, and configuration.

Objective evaluation: The initial results of the objective assessment of the simulator demonstrate the high construct validity of the model as it was able to realistically discriminate between the participating groups' levels of technical skills and experience. The novice medical student group was initially and expectedly not able to get into a constant workflow. The participants of this group as well as some neurosurgical residents often needed to ask for reassurance and rethink steps. One of the main struggles was the orientation in the operative field and hand-eye coordination while using the microscope. This highlights the important role that high-fidelity synthetic simulators can play in

surgical training, as they can help in understanding spatial relationships during surgery and the view through the operating microscope.

The objective structured assessment of each participant's technical skills over the course of four attempts revealed overall near perfect results for expert neurosurgeons in all relevant areas of the simulation, demonstrating the simulator's construct validity. At the same time, considerable and rapid improvements in surgical handling, accuracy and quality was measured among novice medical students and neurosurgical residents, highlighting the efficacy of the simulator as a tool for surgical training.

4.2 Limitations

The subjective assessments of face and content validities is influenced by the different levels of experience of each study participant. Novice medical students and neurosurgical residents with no experience in cerebral aneurysm procedures are limited in their interpretation of the simulators as they are not able to compare the simulation to real-life experiences. Aspects like optics and haptics of the model could only be assessed on a limited database of experience. On the other hand, the group of advanced neurosurgeons who have performed several clippings of aneurysms before had no extensive improvement of skills by using the synthetic training model. This affects their experience with the simulation, but not the simulator's quality, because it was developed to train inexperienced neurosurgeons, who benefit the most by training with the simulator. Another limitation of this simulation is the absence of blood flow and complications encountered during the clipping process. While the improvement in the performances of students and neurosurgical residents suggest that the simulator possesses a high efficacy as a training tool, it is essential to post-training performances of the participants in real-life scenarios would need to be evaluated to see if improvements on the simulator translate to real-world skill enhancements.

4.3 Conclusion

The creation and incorporation of an innovative, budget-friendly neurosurgical simulator, outlined in this research, signifies a major progress in the realm of neurosurgical learning and practice. This simulator offers a practical solution for developing and maintaining surgical skills in managing middle cerebral artery aneurysms, as traditional surgical caseloads decrease and the demand for alternative training methods grows. The simulator's emphasis on anatomical accuracy, realistic touch, and including important surgical steps has been shown to greatly help neurosurgeons of all skill levels improve their microsurgical skills and confidence. The simulator's potential to bridge the gap between traditional training methods and modern neurosurgical education is highlighted by the positive

feedback and objective improvements seen in participants' surgical abilities. The research results support the idea of deliberate practice, showing that concentrated, repetitive practice in a controlled setting can speed up learning and improve the skills of beginner surgeons, leading to better patient safety. Nevertheless, the constraints discovered, such as the absence of authentic blood flow replication and the differences in how well participants can judge the simulator's realism according to their familiarity, point out directions for upcoming studies and improvements. Adding dynamic blood flow and interactive complications to the simulator could enhance its educational value and realism even more.

In conclusion, this work offers convincing proof of how synthetic simulators are effective and practical for training in neurosurgery. The continuous development of the field will require the essential use and advancement of training tools to train future neurosurgeons. Ensuring that they have the required skills and confidence enables us to uphold high levels of patient care and adjust to the evolving field of neurosurgery. Future studies focused on the long-term impacts of simulator training on clinical outcomes will be essential in validating the role of simulation-based education as a cornerstone of neurosurgical training programs.

5. Summary (German)

Das Fachgebiet der Neurochirurgie erfordert erhebliche Expertise und technische Fertigkeiten, die traditionell durch die Erfahrung im operativen Setting erworben worden. Angetrieben durch die Entwicklung alternativer Therapiemöglichkeiten und verschärft durch die Einführung von Arbeitszeitregelungen, ist in den vergangenen Jahrzehnten jedoch ein stetiger Rückgang der chirurgischen Fallzahlen zu beobachten, die jungen Assistenzärzten in ihrer Ausbildung zur Verfügung stehen um eine chirurgische Expertise aufzubauen. Von diesem Trend ist insbesondere die vaskuläre Neurochirurgie betroffen, in der infolge der Einführung endovaskulärer Behandlungsmethoden ein signifikanter Rückgang von mikrochirurgisch behandelten zerebralen Aneurysmen zu verzeichnen ist. Die mikroneurochirurgische Behandlung bleibt jedoch in vielen Fällen auch heute die Methode der Wahl, insbesondere bei Aneurysmen der Arteria cerebri media, was, angesichts der rückläufigen Fallzahlen, die Bedeutung alternativer Ausbildungsmethoden zur Erlangung der chirurgischen Expertise verdeutlicht. In den letzten Jahren wurden verschiedene Simulationsmethoden entwickelt, um dieses Problem zu adressieren. Insbesondere synthetische Simulatoren bieten die Möglichkeit eines fokussierten, praxisnahen "hands-on" Trainings in einer kontrollierten Umgebung. Die Integration solcher Simulatoren in die neurochirurgische Ausbildung scheitert bislang jedoch an mangelnder Realitätsnähe, eingeschränkter Benutzbarkeit und hohen Anschaffungskosten. Ziel dieser Arbeit ist die Entwicklung eines realistischer, effektiven, wiederverwendbaren und gleichzeitig kostengünstigen Simulators für das fokussierte Trainieren der mikroneurochirurgischen Behandlung von Aneurysmen der Arteria cerebri media. Die Kombination aus digitalen Rekonstruktionen, additiven Verfahren, rheologischen Analysen zusammen mit der Expertise erfahrener vaskulärer Neurochirurgen ermöglichte die Schaffung eines hochrealistischen, Simulators, der die taktilen Eigenschaften des lebenden Gehirns präzise wiedergibt, und erstmals die fokussierter Simulation der entscheidendsten Schritte des operativen Verfahrens in einer sicheren Umgebung ermöglicht. Teilnehmer mit unterschiedlichen neurochirurgischen Erfahrungsstufen (sechs Medizinstudenten, vier neurochirurgische Assistenzärzte und zwei vaskuläre Neurochirurgen, n = 12) testeten und bewerteten den Simulator anhand subjektiver und objektiver Kriterien. Die Ergebnisse der subjektiven Bewertung, basierend auf einer 5-Punkte-Likert-Skala, zeigten hohe Gesichts- und Inhaltsvaliditäten in allen Kategorien mit einem Durchschnittswert von 4,9/5.

Die objektive, strukturierte Erfassung der chirurgischen Leistungen zeigte eine hohe Konstruktvalidität des Simulators bei realitätsnaher Reflektion der chirurgischen Fähigkeiten der einzelnen Gruppen. Die Effektivität des Simulators als chirurgisches Ausbildungsinstrument wurde durch eine rapide und signifikante Akzeleration von chirurgischer Präzision und Sicherheit von unerfahrenen Medizinstudenten und Assistenzärzten verdeutlicht.

6. Figures

- Figure 1: Structured workflow detailing the reconstruction, digital editing, additive manufacturing, material research, and crafting process of the model.....11
- Figure 2: Segmentation and volumetric reconstruction of the head with InVesalius3 defined by greyscale boundaries.....13
- Figure 3: A, B) Reusable calvaria, occiput and central console of the skull with an integrated rail-slide system (white arrows), supporting wall elements (yellow arrows) and plug-in mechanisms (red arrows) for attachment and stabilization of the model. C) Additional plug-in and rail-slide mechanisms integrated into the replaceable skull base elements for swift de- and reattachment of the skull base elements containing the Sylvian fissure and MCA aneurysm models.14
- Figure 4: A) Manual digital reconstructions of the anterior clinoid process and B) the optic chiasm in Blender and Meshmixer C) integration of the optic chiasm and supporting socles for the placement of the CAW (green arrow) into the center console of the simulator.....15
- Figure 5: Modifications to the filler density of the 3D printed skull (red arrows) with A) 5% and B) 15% allowing the realistic tactile feedback of the tabula externa and interna during the drilling simulation.15
- Figure 6: A) The reusable central console serves as an anchoring and connecting point for the replaceable skull base parts via clip mechanism at its anterior edge and base (blue arrows) B) the reusable calvaria and occipital region can be attached via plug-in mechanisms (green arrows) and an integrated slide and rail system (red arrow).....16
- Figure 7: A, B) Results of the reusable calvaria and occiput with integrated slide (white arrows) and plug-in mechanisms (red arrows) for attachment of the replaceable skull parts C) empty spaces in in the frontoparietal and occipital parts of the reusable skull for optional integration of a peristaltic pump.....17
- Figure 8: Results of the replaceable skull base elements with connective structures for a stable three-point attachment via clip and slide-rail mechanisms to the phantom's central console (red arrows), the calvaria and occiput (blue stars).18
- Figure 9: A) Pial surface segmentation of the brain in FreeSurfer B) reconstructed 3D mesh of the brain in Blender.19
- Figure 10: Surface mesh of the Sylvian fissure divided into temporal and frontal lobes in Blender....20
- Figure 11: A) 3D printed models of the Sylvian fissure in varying configurations and densities printed with PVA, PETG and B) PLA-filaments C, D) models of the Sylvian fissure separated in frontal and temporal lobes to ensure anatomical accuracy of the negative silicone form.....21
- Figure 12: Testing samples of the Sylvian fissure model casted with A) gelatin Bloom 260 in 12,5% concentration B) Polyvinyl alcohol with 32,5% degree of hydrolysis C) polyacrylamide in 12% concentration and D) candle gel.....23
- Figure 13: Results of the subjective assessment of tested materials regarding their tactile properties by two experienced neurosurgeons derived from a 10-point Likert scale.23

Figure 14: A) bubble-free samples of candle gel with a thickness of 2,5 mm for rheological testing B) 35 mm diameter cutter, 25 mm diameter cutter, 35 mm measuring geometry for cylindrical sample preparation.23

Figure 15: A) Bose Electroforce System used for three-cycle compressions tests B) candle gel samples were placed on the lower surface of the device, which is connected to the load sensor C) rotatory shear rheological measurements were executed on the Thermo Scientific HAAKE MARS rheometer D) candle gel placed between measuring geometry and lower plate of the rheometer.25

Figure 16: A) Stretch vs. stress results derived by implementing compression stresses of (a) 0.2 kPa, (b) 0.6 kPa, and (c) 1.2 kPa on candle gel samples B) stretch vs. stress results of candle gel compared to the results of gelatin 260 Bloom samples in 5%, 7.5%, 12.5%, and 17.5% concentrations.....26

Figure 17: A) Storage and loss modulus B) tangent of the phase angle.....27

Figure 18: A) Negative silicone mold of the Sylvian fissure model B) candle gel-based Sylvian fissure model ready to use after cooling down for 30 minutes.28

Figure 19: A) Results of the Sylvian fissure casting with candle gel (left and right), revealing high anatomical detail and tactile accuracy B, C) the Sylvian fissure model is casted in a single pour, allowing the temporal and frontal lobes to be retracted (blue arrow) and blood vessels and aneurysms embedded within the Sylvian cistern and lateral sulcus.29

Figure 20: A, B) Reconstruction and digital post-processing of the CAW in Meshmixer and Blender with integrated connectors for quick magnetic attachment and replacement of MCA aneurysms C) modified CAW placed into the center console.31

Figure 21: A) Hollowed-out 3D printed model of the CAW B) latex-based CAW model (earlier version) C) finished CAW model coated with latex and embedded in the central console with magnetic adapters attached on both proximal M1 segments.32

Figure 22: A) 3D printed template of an MCA trifurcation with giant aneurysm B) hand-crafted candle wax model.33

Figure 23: A, B) Latex-based MCA bi- and trifurcation aneurysms samples next to their 3D printed templates C) finished MCA vascular tree with aneurysm located at the MCA bifurcation and early temporal branch (green arrow). A small cylindric magnetic connector is attached to the proximal M1 segment to facilitate the attachment to the CAW model.34

Figure 24: A) Initial web-like base structure of the arachnoid membrane created with transparent polyvinyl acetate strings B) finished arachnoid membrane model.35

Figure 25: A) Inner subarachnoid spaces consisting of cisterns and major blood vessels B, C) outer arachnoid membrane model applied to the Sylvian fissure with growing thickness around the Sylvian cistern.36

Figure 26: A) Fresh latex-based dura mater model applied to the right cranial base, B) latex-based dura mater model after several weeks maintaining tactile properties and structural integrity C -E) incision and opening of the dura mater.37

Figure 27: Assembly process of the simulator.....38

Figure 28: A) Simulation setup including a ZEISS OPMI Neuro NC-4 microscope, and microneurosurgical instruments.....	40
Figure 29: Simulation process starting with A) the positioning and fixation of the head in a three-point fixation device B) planning of the pterional craniotomy, burr hole placement, removal of splinters with a bone punch C, D) craniotomy placement, and removal of bone flap E, F) dural incision and opening.....	41
Figure 30: A, B) Microsurgical dissection of arachnoid membrane and opening of the Sylvian fissure C, D) Identifying the anterior clinoid process (blue arrow) and optic nerve (red arrow), visualization of aneurysm, preparation of aneurysm for good neck exposure E, F) successful clipping of a right MCA bifurcation aneurysm.....	42
Figure 31: Main types of research validity based on objective and subjective assessments.....	43
Figure 32: Participants' responses (group 1-3, n = 12) to survey questions on the simulator's general usability derived from a 5-point Likert scale.	49
Figure 33: Average responses of participating neurosurgical residents and neurosurgeons (group 2 + 3, n = 6) on the simulator's educational usefulness derived from a 5-point Likert scale.	49
Figure 34: Average responses of participating neurosurgical residents and neurosurgeons (group 2 + 3, n = 6) on the simulator's realism and their perceived anatomical and tactile accuracies derived from a 5-point Likert scale.....	50
Figure 35: Results of the objective assessment of technical skills in aneurysm clipping. The average scores of the expert, advanced and novice groups' first attempts on the simulator reveal a high construct validity of the simulator as it realistically discriminates and reflects the different levels of experience and technical skills of each group.	50
Figure 36: Objective assessment of technical skills of participating medicals students (MS), neurosurgical residents (NR) and neurosurgeons (NS) over a course of four attempts in critical areas of the procedure over the course of four attempts showcasing a rapid and significant improvement in surgical skills among medical students and young resident.	51
Figure 37: Overview of the objective assessment of technical skills of participating medicals students (MS), neurosurgical residents (NR) and neurosurgeons (NS) over a course of four attempts revealing a rapid and significant acceleration in surgical precision and quality among novice medical students and inexperienced residents.	52

7. Tables

Table 1: List of software programs used for segmentation, reconstruction, and digital post-processing of the model.	11
Table 2: Material samples and concentrations tested and rated by experienced neurosurgeons regarding their resemblance to the tactile properties of the living brain as encountered during surgical procedures.....	22
Table 3: Stretch of different samples in comparison to gel candle after applying 1.2 kPa compression stress.....	26
Table 4: Dimensions, weight, and mechanical properties of the sample in the linear viscoelastic region.	27
Table 5: Participants' (n = 12) average age, and experience in neurosurgery.	39
Table 6: Subjective evaluation and assessment questionnaire completed by each participant via the open source on-line statistical survey web app LimeSurvey.	45
Table 7: Modified version of the Objective Structured Assessment of Aneurysm Clipping Skills (OSAACS).....	46
Table 8: First-time production cost and continued operating expenses of the simulator.	53

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9. Danksagung

Die Danksagung ist in der Version aus Datenschutzgründen nicht erhalten.

10. Ehrenerklärung

Ich erkläre, dass ich die der Medizinischen Fakultät der Otto-von-Guericke Universität zur Promotion eingereichte Dissertation mit dem Titel

„Simulation Training in Neurosurgery:
Development and Evaluation of a Practical Training Simulator
for the Microsurgical Management of Middle Cerebral Artery Aneurysms“

in der Universitätsklinik für Neurochirurgie

mit Unterstützung durch Herrn Priv.- Doz. Dr. med. Belal Neyazi

ohne sonstige Hilfe durchgeführt und bei der Abfassung der Dissertation keine anderen als die dort aufgeführten Hilfsmittel benutzt habe.

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11. Darstellung des Bildungsweges

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Erklärung zur Straffreiheit

Ich erkläre hiermit, nicht wegen einer Straftat verurteilt worden zu sein, die Wissenschaftsbezug hat.

A handwritten signature in blue ink, consisting of several loops and a long horizontal stroke at the end.

Magdeburg, den 02.04.2024