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Face, Content, and Construct Validity of Brain Tumor Microsurgery Simulation Using a Human Placenta Model

BACKGROUND: Brain tumors are complex 3-dimensional lesions. Their resection involves training and the use of the multiple microsurgical techniques available for removal. Simulation models, with haptic and visual realism, may be useful for improving the bimanual technical skills of neurosurgical residents and neurosurgeons, potentially decreasing surgical errors and thus improving patient outcomes.

OBJECTIVE: To describe and assess an ex vivo placental model for brain tumor microsurgery using a simulation tool in neurosurgical psychomotor teaching and assessment.

METHODS: Sixteen human placentas were used in this research project. Intravascular blood remnants were removed by continuous saline solution irrigation of the 2 placental arteries and placental vein. Brain tumors were simulated using silicone injections in the placental stroma. Eight neurosurgeons and 8 neurosurgical residents carried out the resection of simulated tumors using the same surgical instruments and bimanual microsurgical techniques used to perform human brain tumor operations. Face and content validity was assessed using a subjective evaluation based on a 5-point Likert scale. Construct validity was assessed by analyzing the surgical performance of the neurosurgeon and resident groups.

RESULTS: The placenta model simulated brain tumor surgical procedures with high fidelity. Results showed face and content validity. Construct validity was demonstrated by statistically different surgical performances among the evaluated groups.

CONCLUSION: Human placentas are useful haptic models to simulate brain tumor microsurgical removal. Results using this model demonstrate face, content, and construct validity.

KEY WORDS: Bipolar coagulation, Brain tumor, Microsurgery, NeuroTouch, Placenta, Virtual reality surgical simulation

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A wide variety of benign and malignant central nervous system tumors are removed by neurosurgeons using a series of specific microsurgical techniques. These operative paradigms have been developed to maximize tumor resection while maintaining patient safety.[1] Years of resident training involving the resection of large numbers of diverse lesions is a necessary prerequisite to acquire these specific "expert" bimanual skills.[2,3] Surgical simulation using a variety of virtual reality (VR) technologies is being explored to aid in the assessment and training of neurosurgical residents in the removal of cerebral tumors.[4-7] Simulation technology provides multiple opportunities for deliberate practice in safe learning environments in which learners achieve desired outcomes.[3,8] Legal issues and working hour restrictions are contributing factors that are forcing neurosurgical departments to focus on simulation technologies to improve patient care, minimize complications, and change

ABBREVIATION: VR, virtual reality

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FIGURE 1. *Microscopic view of bipolar forceps being used to outline the simulated tumor border seen with a green appearance under the allantoid membrane. Color version available online only.*

the paradigm of learning from a competent to an expertise level of skills acquisition.[3,8]

Simulators using VR technologies with haptic feedback including ImmersiveTouch, developed at the University of Chicago, and NeuroTouch, developed by the National Research Council (Canada) working with the Neurosurgical Simulation Research and Training Centre at Montreal Neurological Institute and Hospital and other research groups, can complement biological models and may be useful to assess resection of cerebral tumors.[4-7,9,10] Although microsurgery techniques can be assessed in simulation VR models, biological models providing high tissue fidelity along with more realistic bleeding would substantially augment the field of technical skills training. Animal models that are used to teach microsurgical skills do not include specific tumor resection scenarios.[11] Biological models specifically developed to study brain tumor resection with the ability to teach microsurgical haptic tool interaction for tumor removal and control of bleeding would advance the field of surgical simulation.

The purposes of this article are (1) to outline the human placenta as a biological, ex vivo, high-fidelity surgical model that can be used to simulate brain tumor resection and (2) to evaluate face, content, and construct validity of this placental model.

METHODS

After approval from the Ethics Committee of the Federal University of Minas Gerais, Belo Horizonte, Brazil, 16 human placentas were collected. Signed informed consent was obtained from expectant mothers and a predelivery infection screening was carried out.

Placental Tumor Model

The placentas used in this study were prepared at the Federal University of Minas Gerais microsurgical laboratory as previously described.[12,13] The human placenta is highly vascularized with an allantois membrane covering the stroma. The variably sized arteries and veins need to be avoided when injecting silicone into the placental stroma to produce the simulated tumor (Dow Corning 3110 RTV Silicone Rubber and catalyzer DALTOCAT 60 N, Dow Corning, Midland, MI). A 25 G × 7/8 in needle was used to slowly inject the silicone solution (1 mL/7 s) 2 mm under the placenta stromal surface. A white silicone/catalyzer solution in a dilution of 7:1 was used to reproduce a tumor mass with a hard, well-defined tumor-tissue border interface. A green silicone/catalyzer solution dilution of 10:1 was used to simulate a less well-defined infiltrative-like tumor. The simulated tumors are visualized beneath the placenta surfaces secondary to the color differences, and the “tumor” borders are easily visualized under microscopic illumination (Figure 1). The 3 vessels of the umbilical cord were cannulated after tumor production and continuously perfused by an infusion pump using colored saline solutions simulating blood as previously described.[12,13] Due to the high placenta stroma vascularization, all simulated tumors were surrounded by multiple arterial and venous vessels. Doppler ultrasound is useful for measuring intravascular flow in the vessels surrounding these simulated tumors.[13]

The simulated brain tumor resection scenarios using this placenta ex vivo brain tumor model are outlined in Table 1. The 3 scenarios assessed in this study were (1) time in minutes necessary for complete microsurgical tumor removal, (2) time in minutes necessary to coagulate a 1.5-mm vessel, and (3) time in minutes necessary to suture the lesioned wall of a 2.0-mm vessel. Eight “expert” neurosurgeons and 8 neurosurgical residents were recruited for this study. Experts were defined as neurosurgeons who performed at least 2 brain tumor microsurgical resections monthly for the previous 2 years. Novice

TABLE 1. **Proposed Training Exercises**

Surgical Simulation Exercise	Learning Activity Proposed	Degree of Difficulty	Figure Illustrating the Activity	Placenta Structure Used
Arachnoid-pia-cortical opening	Bipolar, knife, and scissors microsurgical use under microscopic visualization	Medium	2	Allantois membrane
Tumor debulking and resection	Fine movements with microsurgical instruments	High	3	Created tumor in placenta stroma
Vessel coagulation using bipolar electrothermic cautery	Delicate use of bipolar under microscopic visualization	Medium	4B	Placenta stroma and surface vessels
Vessel suture	Control of massive bleeding: microsuture under microscopic visualization	High	5A	Placenta vessels from 1 mm to 4 mm

TABLE 2. Microsurgical Simulated Exercises and Related Complications

Microsurgical Exercise	Catastrophe Simulation	Occurrence Frequency When Working in the Model	Surgical Maneuver to Practice Treating This Complication
Simulation of brain cortex coagulation	Normal tissue and vessel coagulation outside the excision area	Low	Definition of the target area before starting
Suction device use	Accidental suction of nondesired surgical target structure	Median	Learning and practice using the suction devices
Microscissors use	Artery and vein lesion	Median	Careful cutting and microsurgery vessel repair for larger vessels
Tumor resection	Excessive retraction and lesion of surrounding structures	High	Tumor debulking and resection practice

residents had never performed a brain tumor microsurgical resection. Each participant used standardized microscopic techniques to remove these simulated tumors, coagulate, and/or suture the lesioned blood vessels. To assess face and content validity, each participant evaluated the tasks using a 5-point Likert scale questionnaire after task completion.[3,14,15] Statistical analysis was performed using the Fisher exact test, and $P < .05$ was considered significant. Construct validity was assessed based on the time in minutes required to complete each task, comparing neurosurgeon and resident groups. Statistical analysis for construct validity was performed using the Mann-Whitney U test, and $P < .05$ was considered significant.

RESULTS

All 16 placentas were appropriate for use as simulated ex vivo models for brain tumor microsurgical resection. Placenta preparation and stromal silicone injection to initiate tumor formation was straightforward. Thirty minutes was sufficient for placental vessel cannulation and silicone injection.[12,13] Placentas were used for the simulated tumor resections 24 hours after injection, which allowed the silicone to harden into a solid mass. The silicone/catalyzer dilution injected into the placenta had physical properties depending on the concentration used. A less diluted solution resulted in harder simulated tumors with well-identified borders, whereas adding less silicone to the solution simulated softer infiltrated tumors.

Table 2 outlines some operative issues encountered while participants resected tumors in the simulation model. The opening of the allantois membrane simulates the arachnoid-pia-cortical opening during human tumor resection (Figure 2). The process of resection of a typical simulated brain tumor can be seen in Figure 3. A video demonstration of the resection task is shown in the **Video** (**Supplemental Digital Content**, http://links.lww.com/NEU/A782, which demonstrates microsurgical resection of simulated green tumor embedded in the placenta stroma). Figures 4A and 4B outline vessel bleeding and the use of suction and bipolar coagulation to control

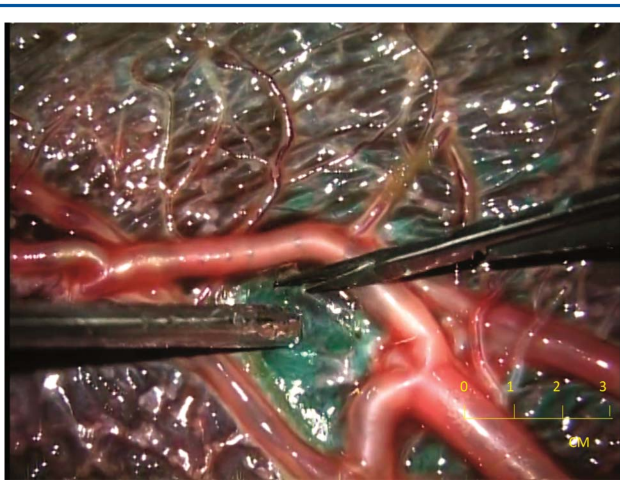

FIGURE 2. *Human placenta stroma with the allantois membrane opening using microscissors simulating microscopic brain tumor surgery. Color version available online only.*

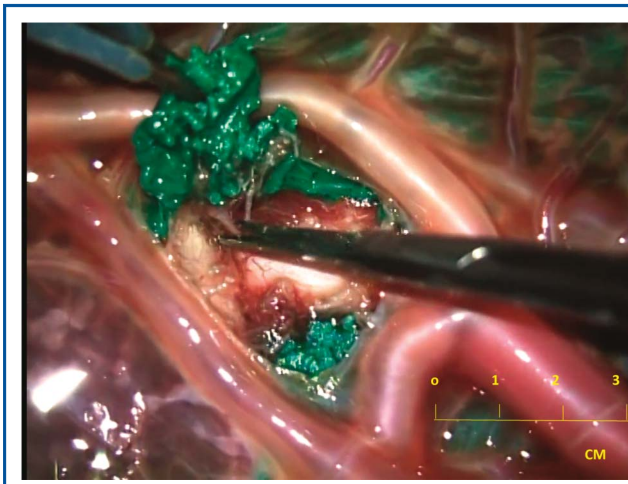

FIGURE 3. *Brain tumor resection using microscopic simulation where the tumor is seen as a green color with attachments to the placenta stroma. Color version available online only.*

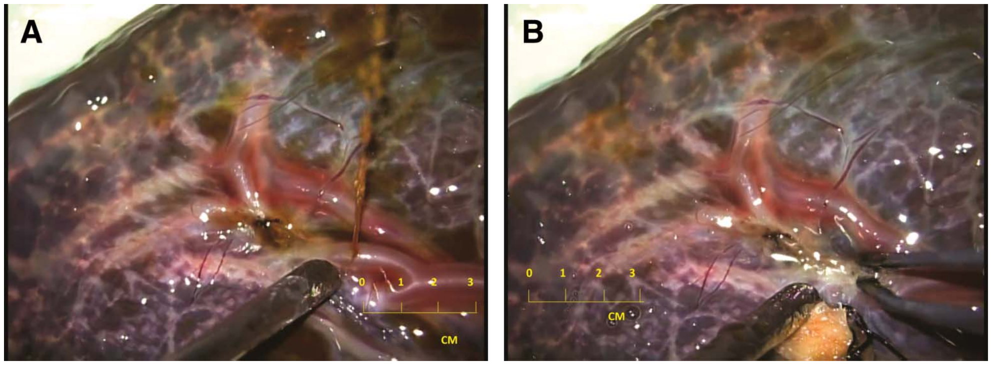

FIGURE 4. A, *microscopic view of a high pressure bleeding simulation from a placenta vessel with use of the sucker.* B, *results of bipolar coagulation of the bleeding placenta vessel. Color version available online only.*

bleeding, and Figures 5A and 5B demonstrate vessel injury and the use of a suture to repair the vessel. These vessel complications occur during human brain tumor operations, and these surgical simulation brain tumor resection scenarios provide opportunities to deal with these potential operative complications. The results of face, content, and construct validity are outlined in Tables 3 and 4.

DISCUSSION

The human placenta is a high-fidelity surgical model that can be used to simulate brain tumor resection. The platform incorporating the simulated scenarios and the time metric used differentiates novice from expert neurosurgical performance, demonstrating face, content, and construct validity. The use of human placenta was described for microsurgical suture training in 1979.[16] Our study is the first to use and validate the use of human placentas as a training model for brain tumor microsurgical resection. Because human tissue was used only after its removal from the body and patients readily consented to its use, ethics committee approval should not be difficult. Biological contamination is an important issue, and appropriate precautions must be taken to avoid contamination.[12,13,17]

VR simulators have been used to assess both the impact of the physical characteristics of the simulated tumor and the bimanual psychomotor metrics involved in tumor resection.[4-7,18-20] The NeuroTouch platform has demonstrated significant differences in neurosurgical bimanual psychomotor performance of medical students, residents, and neurosurgeons based on simulated tumor complexity and bleeding, establishing construct validity.[5,19,20] A comparison of some characteristics of NeuroTouch and the human placenta model are shown in Table 5. VR reality models are continually improving anatomic realism using multiple novel scenarios and can directly assess psychomotor function.[19-21] The major advantage of the human placenta models is the high-fidelity reproduction of surgical events including vascular injury. Arterial and venous blood flow can be simulated by perfusing specific placental vessels with different liquids at various pressures. The use of patties, suture techniques, and hemostatic agents such as Surgicel (Ethicon, Somerville, NJ) to control bleeding along with the ability to assess the role of varying vascular pressure cannot yet be modeled

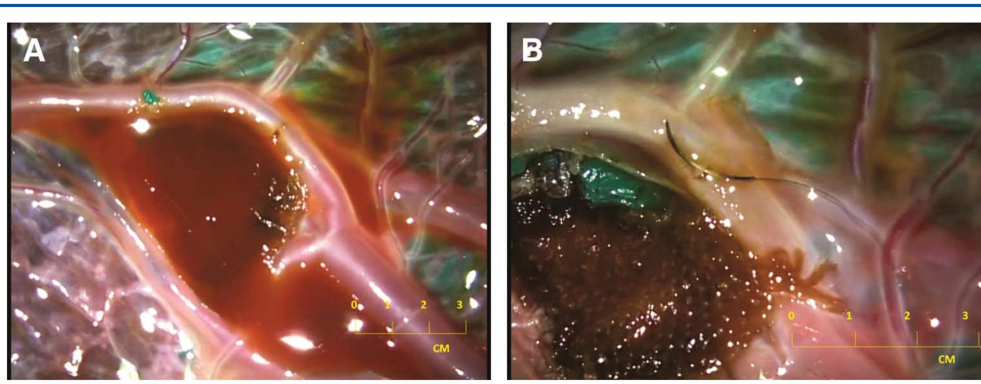

FIGURE 5. A, *microscopic view of a vessel lesion simulation with associated bleeding.* B, *simulation of vessel repair with 9-0 suture needle. Color version available online only.*

TABLE 3. Face and Content Validity[a]

Face Validity	Is the HP Tumor Model Similar to Real Entire Surgery?	Is the HP Tumor Model Similar to Real Microsurgery Tumor Resection?
Experts median answers	3	4
Novices median answers	4	5
P value[b]	.20	.20

Content Validity	Is the HP Tumor Model Similar to Patient Setup in the Operating Room?	Is the HP Tumor Model Similar to Brain Corticectomy?	Is the HP Tumor Model Similar to Microsurgical Brain Tumor Removal Technique?	Is the HP Tumor Model Similar to Real Surgery Vessel Coagulation?
Expert (median)	1	3	4	5
Novice (median)	3	5	5	5
P value[b]	.007[c]	.041[c]	.077	1.0

[a]HP, human placenta. Likert 5-point scale: 5, very similar; 4, similar; 3, some similarity; 2, little similarity; 1, not similar.
[b]Fisher exact test.
[c]P value $< .05$.

on VR simulators, but can be assessed in the placental model. The placenta ex vivo perfusion model also has the potential to reproduce various aspects of the coagulation cascade depending on which blood products (different platelet and/or coagulation factors) are infused. The placental simulation model, along with NeuroTouch, can model bipolar and suction device use. Cost and maintenance are major concerns related to any virtual simulator laboratory setup.

Different types of silicone/catalyzer solutions were tested and allowed the production of simulated tumors with a wide variety of densities and colors. Injection of solutions with more silicone and less catalyzer resulted in an infiltrate into the placenta stroma into its trabeculae and vessels, simulating high-grade infiltrative tumors without defined borders. Solutions with more catalyzer and less silicone tended to form more solid and compact masses, resulting in a well-demarcated border simulating benign lesions. Silicone was used exclusively in this study, but other types of chemical compounds may provide better models for specific simulation.

Strengths and Limitations

Human placentas are readily available and can be used in multiple research environments. Experience in our laboratory has demonstrated that after a week of training, the preparation of placentas for microsurgical procedure takes 30 minutes. The surgical instruments used in all neurosurgical operating rooms during the resection of brain tumors are those used in the placental model to enhance operative realism. Live animal surgical models for the training of microsurgical removal of cerebral tumors have not been extensively developed.[22] The ex vivo human placenta tumor model can be used to simulate a variety of difficult situations encountered during human operations, particularly as related to vessel injury and control of bleeding, as shown in Table 2. Excessive brain tissue retraction should be avoided to minimize neurological complications after brain tumor removal.[23] The human placenta model allows this kind of injury to be visually monitored and assessed, perhaps allowing the trainees to avoid this situation in the operating room.

The placenta model does not reproduce all aspects of modern brain tumor resection. Specific components of placental operative procedures need to be improved, including (1) the use of cavitronic aspiration and suction of tumor tissue, (2) more realistic infiltrative models, (3) the use of bipolar cautery to cauterize microvasculature and the detachment of the tumor from its complex environment,

TABLE 4. Construct Validity

Construct Validity	Time (min) Necessary to Complete Simulated Microsurgical Tumor Removal Without Traction[a]	Time (min) Necessary to Perform Bipolar Coagulation Under Microscopic Visualization of a 1.5-mm Vessel	Time (min) Necessary To Microsuture the Injured Wall of a 2-mm Vessel
Expert median (min-max)	9 (8-11)	1 (1-1)	4 (3-5)
Novice median (min-max)	20.5 (19-22)	3 (2-4)	11.5 (10-14)
Statistical analysis *P* value[b]	<.001	<.001	<.001

[a]Traction was observed by displacement of the human placenta over the working platform.
[b]Mann-Whitney *U* test.

TABLE 5. Ex Vivo Biological Placental Brain Tumor Model Compared With a Virtual Reality Model Such as NeuroTouch

Characteristics	Human Placenta Model	Virtual Model
Cost	Low	High
Brain anatomy reproduction	None	Can be reproduced by a computer
Surgical fidelity	High	Low to medium
Haptic	High	Medium to high, related to tumor-incorporated haptics
Biological contamination	Increased risk	None
Durability of the model	7 days at 5°C	Long with continuous upgrades
Availability	Easy to set up and use	Cost limits availability
Ability to model different kinds of simulation	Can reproduce different surgical tasks	Multiple tumor scenarios can be modeled
Metrics	Limited to time for procedure	Multiple metrics available

(4) microscopic manipulation to create better viewing angles, and (5) prevention of closure of the placental surgical corridor to allow deep tumor tissue visualization.

Validation studies have shown the efficacy of this model as a training tool for "novice" neurosurgical residents. Face and content validity was outlined by the participants concerning the microsurgical aspect of brain tumor surgery. Construct validity was established as the time in minutes to complete a number of simulated operative tasks in the 2 groups studied. Further studies can assess resident learning curves, and proficiency performance benchmarks can be developed for individual resident groups.[24] Predictive and concurrent validity would require substantially larger numbers of participants using multiple centers. Medical student workshops using the brain tumor placenta model could aid in career choices. Haptic biological models could also be used to certify quality maintenance requirements by specialty boards.

Our study results need to be interpreted with caution. First, the short task duration and level of color, stiffness, tumor border distinctness and vessel type, and complexity may not adequately discriminate the quality of performance among our limited number of operators. Second, the use of neurosurgeons and residents from only 1 institution may have resulted in our inability to find more significant differences between the neurosurgeon and resident groups. Failure to incorporate more senior neurosurgical residents in this trial makes it difficult to generalize our data to this group. Serial tracking of residents during training and after graduation may be useful in understanding the sequence of technical skills acquisition during residency and modification of these skills after residents become neurosurgeons. Third, the lack of defined metrics outside of time to complete specific tasks does not allow for the quantization of psychomotor activity, which is rather advanced in VR simulators such as NeuroTouch.[3-7,19,20,24] To maximize expertise training, this placental model could play a very important role as a hybrid model (between VR simulators and the patient) by allowing participants who have obtained defined proficiency-based benchmarks on a VR simulator, such as NeuroTouch to be further tested on an ex vivo biological model before being assessed in operating room situations.[25] Fourth, although this study was focused on an assessment of performance of expert and novice groups, it is clear that without the demonstration that biological simulators, such as the placenta model, enhance resident operating room performance, their use will be limited.[26]

CONCLUSION

The human placental brain tumor microsurgical resection model is a high-fidelity training model that may have significant potential in the evaluation and training of neurosurgical residents. Our studies have demonstrated face, content, and construct validity, suggesting that this model deserves further exploration to assess its potential in neurosurgical teaching.

Disclosures

This work was supported by the Di Giovanni Foundation, the Montreal English School Board, the B-Strong Foundation, the Colannini Foundation, and the Montreal Neurological Institute and Hospital. The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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COMMENTS

Simulation has become widely accepted as a selection and training tool in many medical and surgical specialties. Recently, it has gained great interest even in the neurosurgical community, where some new high-technology systems have been developed to specifically train and assess our younger colleagues. The authors suggest an innovative tool that can be added to the simulation armamentarium; it is interesting to note that alternative systems are possible, representing a simple and relatively inexpensive option that can be used as a training platform for medical students, residents, and junior staff neurosurgeons. Although placentae might be not so easy to procure at many neurosurgery departments, they might represent a useful tool to develop some specific technical skills, especially when they are dissected using the operating microscope.

At the Besta NeuroSim Center, we adopted a combined approach in which all top-notch, 3-dimensional haptic feedback neurosurgical simulators are used by students and residents who can also learn and practice some surgical skills by means of a dedicated operating microscope and task-specific manikins.

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Alessandro Perin
Milan, Italy

The use of simulation to prepare neurosurgeons with the technical and decision-making armamentarium necessary to carry out safe and effective surgery is quickly progressing from merely accepted to mandatory. Before we rush into wide adoption, it makes sense that we rigorously evaluate each model. This paper makes a solid effort to validate the placental model. The advantages of this model include its wide availability, economy, and high tissue fidelity to brain tissue. The use of a variety of forms of validation to show that it provides a good simulation experience is important. The biggest issues with simulators are related to the transferability of the skills by the user to actual practice and to the ease of use and availability of the simulator (since if it cannot be easily accessed, the first issue is a non-issue). On this count, the model stands up well.

Here at the Barrow Neurological Institute, we have established an ongoing process to obtain placentas and have established a variety of models for aneurysm clipping, bypass, sylvian dissection, and carotid endarterectomy, among other uses. The use of the model for brain tumor practice is yet another place where this low-cost innovation can have a real impact. In an age of increasing costs, I applaud the senior author of this paper for helping popularize a model that can be inexpensively and widely used to improve clinical practice.

Peter Nakaji
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