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Research Article
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An expandable chamber for safe brain retraction: new technologies in the field of transcranial endoscopic surgery

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Abstract: Neurosurgery is a highly specialized field: it often involves surgical manipulation of noble structures and cerebral retraction is frequently necessary to reach deep-seated brain lesions. There are still no reliable methods preventing possible retraction complications. The objective of this study was to design work chambers well suited for transcranial endoscopic surgery while providing safe retraction of the surrounding brain tissue. The chamber is designed to be inserted close to the intracranial point of interest; once it is best placed it can be opened. This should guarantee an appreciable workspace similar to that of current neurosurgical procedures. The experimental aspect of this study involved the use of a force sensor to evaluate the pressures exerted on the brain tissue during the retraction phase. Following pterional craniotomy, pressure measurements were made during retraction with the use of a conventional metal spatula with different inclinations. Note that, although the force values necessary for retraction and exerted on the spatula by the neurosurgeon are the same, the local pressure exerted on the parenchyma at the edge of the spatula at different inclinations varied greatly. A new method of cerebral retraction using a chamber retractor (CR) has been designed to avoid any type of complication due to spatula edge overpressures and to maintain acceptable pressure values exerted on the parenchyma.

Key words: Brain retraction; Spatula; Brain retractor design; Brain retraction injury; Retraction complication; Transcranial endoscopic surgery

1 Introduction

It is estimated that up to 24 530 brain tumours were identified in the USA alone in 2021, leading to 18 600 deaths (Siegel et al., 2021). The main treatment for this pathology is surgery. Neurosurgery is a highly specialized field: it involves surgical treatment in risky anatomic locations and requires navigation and often manipulation of noble structures that are difficult to access or intolerant to manipulation (Ganly et al., 2005).

Thanks to scientific and technological progress, new surgical techniques in brain surgery have been developed that minimize brain trauma and broaden the surgical indications even for more complex pathologies, allowing better results, shorter recovery time, and a better quality of life (Nicolai et al., 2008; Devaiah and Andreoli, 2009; Eloy et al., 2009; Fu et al., 2016; Rawal et al., 2016).

Endoscopic skull base surgery (ESBS) is a new evolving field in which the aim is to access the skull base and intracranial areas in a minimally invasive way. Operational complexity has been increasing significantly as the advantages of endoscopic vision have been applied to different skull base areas to treat complex intracranial pathologies. With the increase in the duration of surgery, the need for an endoscope holder has also become evident. Robotics has been applied to multiple surgical specialties, and for the head and neck area robotic tools have been designed primarily for thyroid or transoral surgery (O'Malley

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and Weinstein, 2007; Garg et al., 2010; Szold et al., 2015).

Preclinical cadaver studies performed with the da Vinci Surgical System (Intuitive Surgical, Inc., UK) found that this instrument has various disadvantages in neurosurgery (Blanco and Boahene, 2013). Therefore, while robotic surgery approaches have potential utility in neurosurgery, significant improvements are needed to enable them to be used safely (Iwata et al., 2011; Bertelsen et al., 2013; Hannaford et al., 2013; Smith et al., 2016). Robotic technology has also been applied to paediatric epilepsy surgery, transventricular surgery, and deep brain stimulation (Hoshide et al., 2017; Nelson et al., 2020).

Although many robotic prototypes dedicated to endoscopic skull base surgery have been described, their application has been limited by their large dimensions, difficult control, and limited precision. Current robotic solutions for endoscopic skull base surgery are hindered by their excessive dimensions, problematic safety systems, and extended surgical time (O'Malley and Weinstein, 2007; Garg et al., 2010; Carrau et al., 2013; Hannaford et al., 2013). Many of these devices have been conceived for a minimally invasive transnasal approach to the target, exacerbating the shortcomings of the currently available robotic systems. The big innovation of our new endoscopic device is that it is suitable not only for transnasal and endoventricular surgery, but also for transcranial surgery. Furthermore, the size and dynamism of the device presented in this paper allow it to be used not only for tumour biopsy, but also for extensive endoscopic tumour removal. Although all robotic platforms for neurosurgery have potential capabilities, there is no currently focus on a system for retraction of brain tissue.

Cerebral retraction is frequently necessary to reach deep-seated brain lesions but can cause damage such as oedema, vascular lesions leading to haemorrhage or ischemia, and direct damage to the surrounding cortex (Zhong et al., 2003; Marenco-Hillembrand et al., 2020). The incidence of brain retraction lesions is estimated to be about 10% in skull base surgery and 5% in vascular operations (Andrews and Bringas, 1993). Several improved retractors have been developed, but these instruments may still cause injury (Zagzoog and Reddy, 2020).

The main existing retractors are surgical spatulas and tubular retractors (Assina et al., 2014; Eichberg et al., 2020; Shapiro et al., 2020). Both are risky: spatulas can cause damage to the cortex and subcortical substance, particularly at the level of the edges (Ramorino et al., 2022); tubular retractors were developed to distribute the pressure over the cylindrical surface, in an attempt to reduce potential injury to the parenchyma, which are preferable to conventional ones for deep-seated lesions because they dissect and push away the fibre tracts rather than traverse them. In particular, they are placed in the transcortical area, unlike in all the other retraction methods. A small corticectomy is performed with white matter dissection linearly along the lengths of the white matter tracts, usually using the tip of the navigation tool. Then, a custom-built dilator is placed into the barrel of the tube and advanced until the lesion is reached. These innovative design reduces damage to surrounding tissues, but they are still associated with cytotoxic oedema and cell damage (Bander et al., 2016).

Up till now, there are few reliable solutions, not even targeted robotic solutions, that prevent possible retraction complications. Current solutions do not specifically consider the retraction pressure, unlike our new device which allows a dynamic expansion of the opening to control the cerebral retraction. Recently, soft robotic approaches in robot-assisted brain surgery have been proposed by Kim et al. (2019), in which a ferromagnetic soft continuum robot for minimally invasive robotic surgery in deep areas was suggested.

The aim of this present study is to design an innovative expandable chamber, suitable for either the microscope or the endoscope, or both, providing safe retraction of the surrounding brain tissue. To achieve these results, an accurate preclinical phase study was carried out in collaboration with a multidisciplinary team. It is important to highlight that these chambers allow the safe passage of surgical instruments including an endoscope guided by a robotic holder.

2 Design and fabrication: clinical requirements & concept design

The proposed chamber retractor (CR) operates safely, guaranteeing a gentle tissue displacement and suitable force output and biocompatibility. The chamber is designed to be inserted close to the intracranial point of interest; once it is positioned in the area of

interest, it can be opened. This procedure should guarantee an appreciable workspace similar to that of current neurosurgical operations. Regarding the work area, the necessary surgical retraction for brain tumours of 15–29 mm in diameter must be 12–28 mm (Shapiro et al., 2020). The ideal chamber should therefore allow this range of cerebral retraction values to permit adequate passage of the necessary surgical instruments.

Another factor to be considered is the pressure exerted by the retractor device on the surrounding tissue because of its importance in ensuring safe chamber expansion and consequent reliable displacement of the parenchyma. Note that the intraoperative forces exerted during tumour excision are highly variable and depend on various factors, including the consistency of the pathological tissue itself and the type of surgical approach adopted. In this context, an in vivo study by Bekeny et al. (2013) showed that, during transnasal endoscopic excision, the forces varied from 0.1 to 0.5 N, with maximum peak forces of up to 2.12 N. Aggravi et al. (2016) studied the tissue-instrument interaction, reported a range of forces between 0.5 and 6.0 N. In a review of 13 studies, Golahmadi et al. (2021) documented that the mean maximum force produced by manual instruments was 1.48 N; and three studies reported a mean maximum retraction force of 2.5 N. An ideal retractor should provide force values similar to those reported in current surgical procedures, i.e., with a maximum of 3 N, to ensure safe use.

Although many published articles indicated that maximum force values should not be exceeded during cerebral retraction, it would be more appropriate to consider and quantify the specific pressure exerted on the brain tissue, as it can vary in different brain zones depending on the instruments and practical procedures involved in different methods. The same force applied by instruments of variable geometry can result in significantly different specific local pressures exerted on the brain. Also, a high displacement rate used to reach the same brain retraction value can generate more damage.

To illustrate this, it is necessary to consider the importance of the specific position of the retractor on the parenchyma: an incorrect inclination would lead, with the same force applied, to a localized pressure near the edge of the spatula, which was much higher than that near the flat part of the spatula. Figs. 1a and 1b showed an example of correct use of the spatula where the differences between the contact pressures exerted on the parenchyma by the spatula in its central flat area, highlighted in green, are minimal compared to those on the edge of the spatula, in the area highlighted in yellow. Figs. 1c and 1d showed two examples of incorrect positioning of the spatula, although the force retraction exerted by the surgeon is the same in these cases, the specific local pressures on the edges of the spatula (orange and red areas) are much higher than those generated in the case of the correct spatula position.

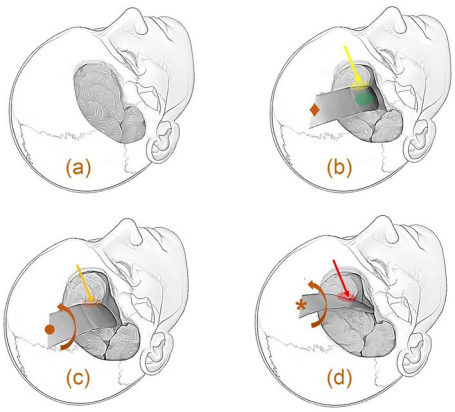

Fig. 1 Examples of brain retraction by spatula at different angles of rotation around its own axis. (a) Unstressed brain configuration. (b) Correct use of the spatula. (c) Incorrect position of the spatula with small rotations generates overpressures at the edge of the spatula. (d) Incorrect position of the spatula with high rotations generates high overpressures at the edge of the spatula. Yellow arrow: area of pressure at spatula edge in correct position; Green circle: area of pressure at spatula flat area in correct position; Orange arrow: area of pressure at spatula edge in incorrect position (small rotation); Red arrow: area of pressure at spatula edge in incorrect position (high rotation) (Note: for interpretation of the references to color in this figure legend, the reader is referred to the web version of this article).

For this reason, the use of the spatula can cause damage to the cortex and to the subcortical substance, particularly in relation to the edges. Tubular retractors are the most recent solution for cerebral retraction described in literature, but they are still associated with cytotoxic oedema and cell damage (Bertelsen et al., 2013). Further, brain retraction can cause local pressure that produces a local deformation of brain tissue for a finite period of time. Such deformation may result not only in ischaemia, but also in mechanical damages, including distortion of neuronal fibres and tearing of the pial-arachnoid structure.

To overcome this problem, we propose a new method of cerebral retraction using a new CR. The design aims to reduce as much as possible any type of complication related to overpressure at the spatula edges and to maintain safe values of pressure exerted on the parenchyma. This was a preliminary study in which the device was tested by simulating the pterional approach, as it is the most commonly used approach in neurosurgery. Other tests on this device are in progress, including the simulation of other neurosurgical approaches to the exploitation of other workspaces, considering the different positions where a tumour could exist, e.g., more superficial or deeper in the skull base. Changes can be made to the length or width of the device. The length can be chosen on the basis of both the type of approach adopted and, above all, the location of the lesion (superficial versus deep).

Materials for the construction of the retractor and actuation methods should guarantee safety and biocompatibility of the device in surgical operations. The materials used for the construction of the present retractor device are biocompatible with humans and have adequate mechanical stiffness allowing safe contact with brain tissue through the use of elastomeric material.

The device has been made of non-transparent biocompatible polymeric material (poly(lactic-acid) (PLA)) covered with a transparent silicone membrane to ensure safe contact with the brain (Fig. 3a). However, it would be possible to use a transparent polymeric material such as polycarbonate (PC) or polyethylene terephthalate glycol (PETG) to enable the state of the brain tissue to be kept under control throughout the surgery. This is a fundamental and unique aspect to avoid any contusions or intraoperative haemorrhages.

A possible concern is that although the chamber secures the surrounding parenchyma, it restricts the working space. When working with an endoscope, the space becomes narrower because this instrument allows excellent visualization, but this is to the detriment of the working space. Furthermore, when an endoscope is used, there is a risk that this instrument may unintentionally cause trauma to the surrounding brain since, however small, the endoscope is still larger than other neurosurgical instruments such as bipolar forceps or an aspirator. Therefore, the chamber protects the brain while guaranteeing the working space suitable for surgery. The thickness of the chamber is about 2 mm; therefore, the effective space reduction is only a few millimetres. Consequently, we can state that the reduction of the working space by 2 mm is offset by the reduction in the risk of traumatic damage to the cerebral parenchyma.

The operation of the new CR device is illustrated schematically in Fig. 2. The CR, in its closed configuration, has a rectangular section with dimensions chosen according to the required retraction and work area. For illustrative purposes, we report the experimental results related to a CR with a thickness of 4 mm, width of 40 mm, and length of 60 mm. Fig. 2a showed the position of a closed chamber inserted at the intracranial point of interest. Subsequently, the chamber is opened, as shown in Fig. 2b. The configuration of the brain retracted by the CR was shown in Fig. 2c.

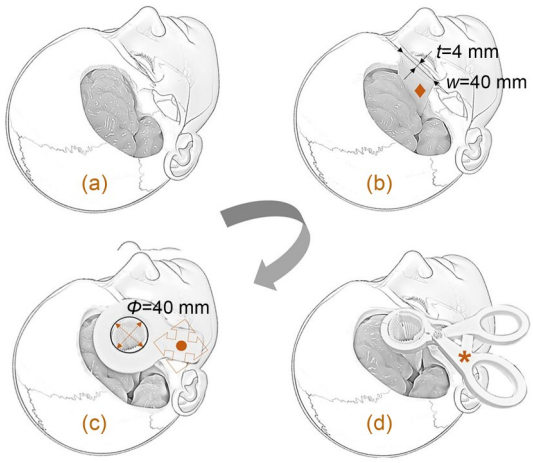

Fig. 2 Principle of operation of the chamber retractor (CR). (a) Unstressed brain configuration. (b) Insertion of retractor in the area of interest. (c) Device opening for brain retraction. (d) Configuration of brain retracted by CR locked at 40 mm diameter. *t*: thickness; *w*: width; *Φ*: diameter; *: "Klemmer" type forceps.

The CR device and the accessories for its use was shown in Fig. 3. Opening the device can be performed manually or using "Klemmer" type forceps (Fig. 3b).

The use of forceps can facilitate the management and opening of the chamber allowing multiple opening levels, giving more control over retraction pressure than the use of a metal spatula. This is very important because it avoids unwanted local pressure peaks. The expanded retractor anchors itself onto the cranium bone and displaces brain tissue to create a passage for other tools to access the site of surgical interest.

Once expanded, the chamber is locked to the desired diameter with a "cover" accessory (Fig. 3c). The cover has a projection that, if necessary, can be

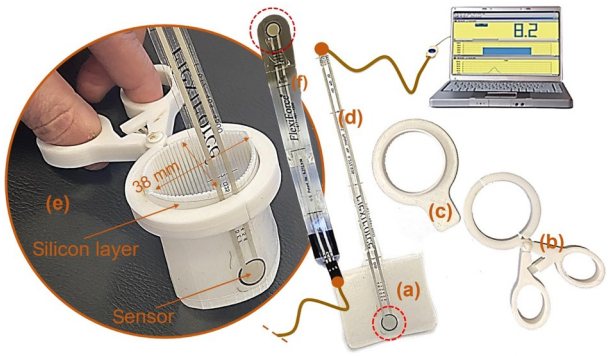

Fig. 3 Chamber retractor (CR) device and accessories. (a) CR. (b) "Klemmer" type forceps for opening the device. (c) Cover accessory for locking the opening at the desired diameter. (d) Optional addition of a retractor fixing system with a pressure sensor. (e) Picture of CR assembly. (f) Conventional metal spatula with pressure sensor.

used to attach it to a retractor fixing system such as the Leyla retractor currently used to install surgical spatulas (Figs. 3d and 3f).

In Fig. 3c, for illustrative purposes, the size of the new chamber has a passage diameter of 20 mm. The size can be increased by increasing the size of the retractor, until a passage of about 40 mm in diameter is obtained (Fig. 3e). Unlike when performing retraction using a metal spatula, with this new device the neurosurgeon can still move and tilt the chamber, achieving a better view of the target without causing pressure increases due to effects on the edges.

3 Experimental tests

One cadaver head was used for the experimental test. The specimen originated from the voluntary body donation program of the Center for Anatomy and Cell Biology of the Medical University of Vienna (Austria). The donor provided informed written consent before death for the body to use in medical education and research. The specimen was alcohol-preserved and dissected in the Anatomical Training Centre "Luigi Fabrizio Rodella" at the University of Brescia. Arterial systems were injected with red-stained silicone. The head was secured with a Mayfield three-pronged headboard and a pterional craniotomy was performed. This approach is one of the most commonly used by neurosurgeons because by opening the Silvian fissure, it allows the structures of the anterior and middle cranial fossae to be reached, minimizing cerebral retractions. This craniotomy is called "fronto-temporo-sphenoid" or "pterional" because the keyhole point is the junction of four bones inside the skull: the frontal, temporal, large wing of the sphenoid, and parietal bone.

The experimental activity involved the use of a force sensor (Fig. 3d) to measure the pressures exerted on the brain tissue during the retraction phase. A digital force measuring system (FlexiForce, Teskcan, Inc., South Boston, MA, USA) was used in retraction mode comparing two configurations: (1) a conventional metal spatula (Fig. 3f) and (2) the new CR (Fig. 3a). The FlexiForce sensor was attached to the new device, as shown in Fig. 3a. The measuring area of the sensor, about 7–8 mm^2, was located near the tip of the spatula and in the centre of its width. The sensor was calibrated using a linear calibration technique with weights between 50 and 150 g, according to the manufacturer's guidelines.

The only point of contact measured was the point of maximum pressure on the chamber, as the pressure sensor was inserted in the area of maximum pressure (maximum crown and distal area).

Fig. 4 showed the insertion steps of the retractor/chamber, as follows: (1) insertion of the CR in the

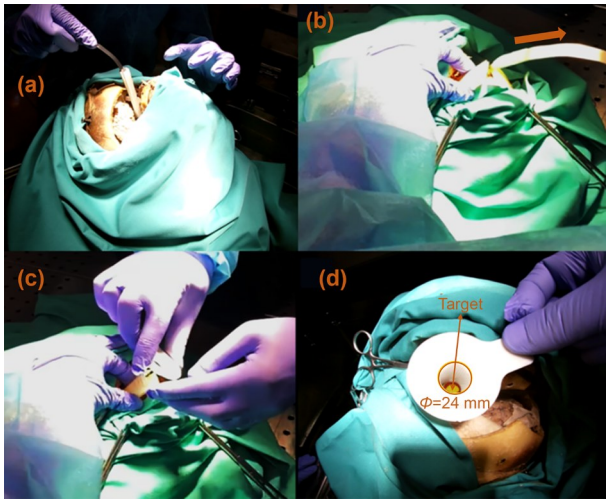

Fig. 4 Brain retraction using the new chamber retractor (CR) device. (a) Insertion of the chamber retractor in the area of interest using a metal spatula. (b) Removal of metal spatula for keeping the CR in position. (c) Brain retraction up to the desired diameter by manual opening of the CR. (d) Insertion of locking cover (yellow sphere simulates lesion area). *Φ*: diameter (Note: for interpretation of the references to color in this figure legend, the reader is referred to the web version of this article).

area of interest using a metal spatula (Fig. 4a); (2) removal of the metal spatula and maintenance of the CR in position (Fig. 4b); (3) manual opening of the CR (Fig. 4c) up to the desired measurement. This operation could also be carried out by using "Klemmer" forceps (Fig. 3b); (4) insertion of the closing cover (Fig. 4d).

A 10-mm-diameter target yellow sphere was inserted into the brain parenchyma to simulate the lesion area (Fig. 4d) within the working area created by the expansion of the chamber. The same type of retraction was repeated using a spatula in a standard curvilinear configuration, equipped with the same digital force measurement system (Fig. 5). The retraction value was about 7–8 mm.

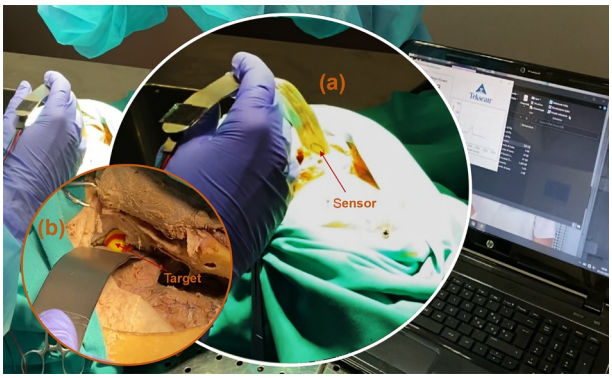

Fig. 5 Brain retraction by conventional metal spatula. (a) Insertion of spatula. (b) Brain retraction by manual displacement of the spatula, with yellow sphere simulating lesion area (Note: for interpretation of the references to color in this figure legend, the reader is referred to the web version of this article).

Note that the tests were not performed in vivo, but on brain samples, and therefore, some factors such as deliquoration were not evaluated. Consequently, to minimize bias due to the stiffness of the cadaver after formalin fixation, the device was also applied to a preclinical model currently used in neurosurgical training with very similar characteristics to that of a live brain. This model was provided by UpSurgeOn S.r.l. (Milan, Italy) (Fig. 6).

4 Results and discussion

Fig. 7 showed the experimental test results related to the retraction measurements performed following the pterional craniotomy using the conventional metal

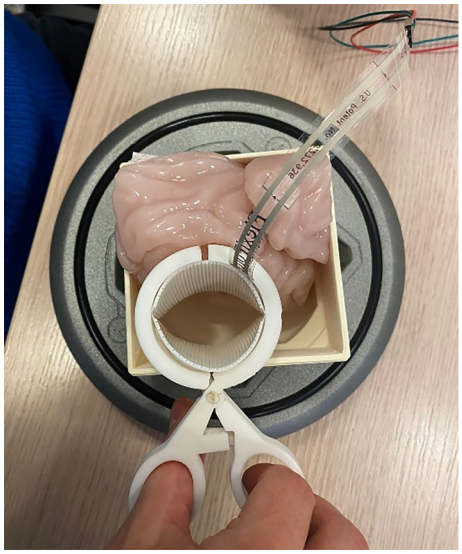

Fig. 6 Tests performed on a preclinical model made by UpSurgeOn S.r.l.

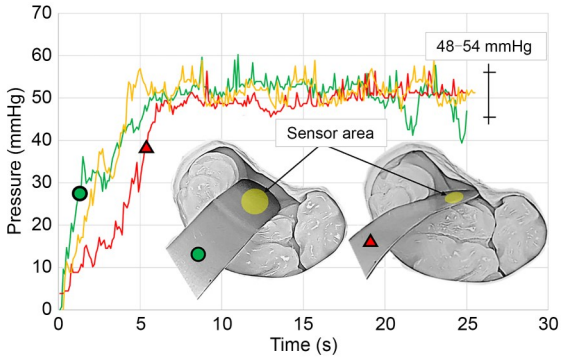

Fig. 7 Pressure exerted on the brain tissue during retraction detected by the sensor applied to the flat part of a metal spatula. Yellow circle represents sensor area of pressure; orange represents the pressure exerted on the flat part of the spatula; red represents the pressure exerted on spatula handle in incorrect position; and green represents the pressure exerted on spatula handle spatula handle in correct position. 1 mmHg=133 Pa (Note: for interpretation of the references to color in this figure legend, the reader is referred to the web version of this article).

spatula, as detailed in Fig. 3. Three curves representing the pressure trend, expressed in mmHg (1 mmHg= 133 Pa), were estimated with the same retraction (about 7–8 mm), but at different spatula inclinations. During these operations the force sensor measurements were similar, with values of about 48–54 mmHg. Although the pressure exerted on the parenchyma was similar, note that this value was measured in the flat part of the spatula, i.e., in the area where the force sensor was inserted (highlighted in yellow in Fig. 7). Although

the force values necessary for retraction and exerted on the spatula by the neurosurgeon are the same, the local pressure exerted on the parenchyma at the edge of the spatula varies with different inclinations. The neurosurgeon cannot detect this variation, and therefore, the possibility of acting safely while respecting the limit pressure forces would certainly be an advantage. However, the local pressure is not easily quantified experimentally due to technological limitations, but an incorrect inclination of the spatula or its incorrect movement in the retraction phase can produce local pressure values much higher than expected. The pressure exerted on the edge of the spatula is very difficult to measure directly using force sensors due to the shape of the spatula. For this reason, accurate pressure values were determined using finite element software.

In the literature, there is a lack of specific data on this topic, so to estimate these values, a structural analysis was carried out using specific simulation software. A brain model was generated from a three-dimensional (3D) scan performed in a hospital with a real human brain sample using Meshmixer software (https://meshmixer.com) (Fig. 8). The model was then meshed using the 3D Mesher software of Autodesk Moldflow© (https://www.autodesk.com/products/moldflow/overview). The mesh file (about 5 million elements) was then imported into the MSC software Marc-Mentat© Finite Element Method (FEM) (Hexagon, Stockholm, Sweden), together with that of a modelled spatula (Fig. 8a). After some trials to verify the consistency of the results and increase the precision of the simulation, the brain model was cut and only a small part was simulated (Figs. 8a and 8b). In this way it was possible to have a much finer mesh with the same number of elements.

A structural analysis was performed assuming a retraction of about 7 mm. The mechanical behaviour of the brain tissue is very hard to model. Possible solutions have been found to be strongly dependent on selected boundary conditions (Rashid et al., 2013; Budday et al., 2015; de Rooij and Kuhl, 2016).

The chosen mathematical model was taken from the study "Numerical Models of Blunt Dissection and Brain Retraction for Neurosurgery Simulations" (Chen, 2017) – a generalized Maxwell model with added consideration of inertial terms. The Maxwell model scalars used in the Prony series are given in Fig. 9.

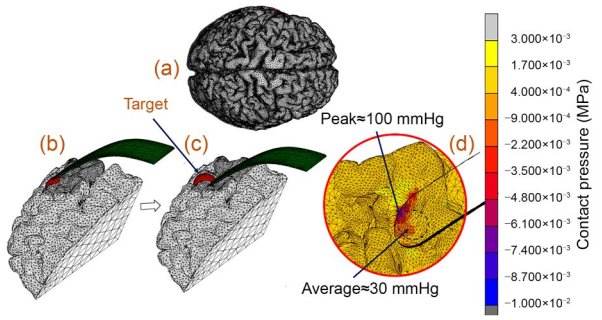

Fig. 8 Brain structural analysis by simulation software. (a) Human brain 3D scan performed by Meshmixer software. The model was then meshed by Moldflow© software from Autodesk. (b) Meshed brain portion and spatula. (c) Meshed brain portion retraction by spatula. (d) Contact pressure of the retraction determined by Marc-Mentat© FEM software. 1 mmHg=133 Pa. 3D: three-dimensional; FEM: Finite Element Method.

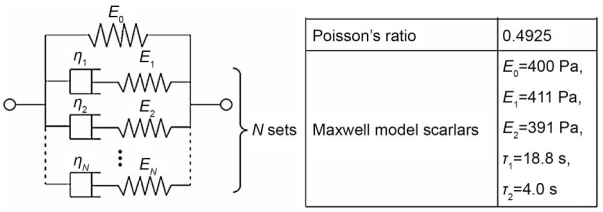

Fig. 9 Generalized Maxwell model and Maxwell model scalars. E_i: elastic moduli; η_i: viscosity; τ_i: relaxation time.

The time (t) dependence of the brain tissue elastic modulus was modelled by the Prony series (Eq. (1)):

$$E(t)=E_0\left[1-\sum_{i=1}^{n_i}e_i\left(1-\exp\left(-\frac{t}{\tau_i}\right)\right)\right], \quad (1)$$

where E_0 is the instantaneous modulus of the material, n_i is the number of Maxwell terms, and (e_i, τ_i) are the Prony coefficients (e_i is the ith Prony constant for the ith Prony retardation time constant τ_i). The Prony coefficients can be understood as follows: e_i is the $E(t)$ percentage change in each term of the Prony series whereas τ_i is the discrete time at which the term of the Prony series intersects the curve of the experimental data, or else the relaxation time η_i/E_i. The results of the analysis showed that the pressure felt by the tissue close to the edge of the spatula was around three times higher than the pressure felt by the area beneath the centre of the spatula and close to the edges (Fig. 8d). This is only an estimation, but it clearly highlights the aforementioned problem. Note that the FEM results

agree with the pressure values given by the sensor attached to the metal spatula during the retraction measurements performed following the pterional craniotomy (Fig. 7).

As mentioned above, although tubular retractors have been proposed as innovative tools for reducing damage to surrounding tissues, they are still associated with cytotoxic oedema and cell damage (Bander et al., 2016).

One of the limitations of tubular retractors is their fixed dimensions, i.e., they are built in a "static" way to be inserted into the skull with a stable dimensional conformation. Our proposed innovative retractor device is instead "dynamic," i.e., it can be inserted closed and then opened according to the required dimensions – the optimal condition for the surgeon. Furthermore, tubular retractors have not been tested for use in transcranial endoscopic surgery, which was the main use intended for our new instrument.

Fig. 10 showed the pressure measured by the sensor applied to the new retractor device in the experimental retraction performed according to the insertion steps described above (Fig. 4). The trend of the pressure detected by the sensor at different time points during the use of the CR is plotted. The chamber, initially opened to about 5 mm (step S1), produced a pressure value of about 40 mmHg. After a short period of maintenance at this opening, relaxation of the tissue led to a reduction in the measured pressure to about 18 mmHg. Subsequently, the opening was further expanded to 15 mm (step S2) and then to its final value

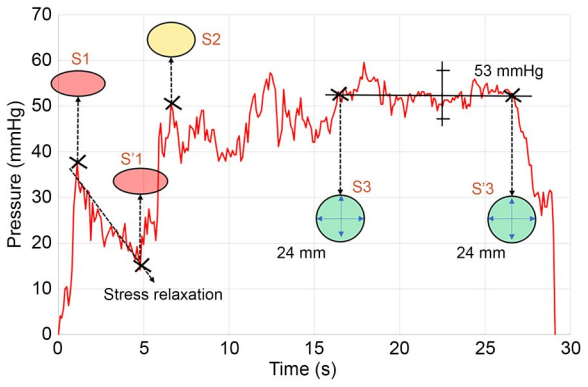

Fig. 10 Pressure detected by the sensor at different time points during the use of the chamber retractor (CR). S1: chamber opening to 5 mm; S'1: 5 seconds after chamber opening to 5 mm; S2: chamber opening to 15 mm; S3: chamber opening to 20 mm; S'3: 10 seconds after chamber opening to 20 mm.

of 20 mm. In the maximum expansion configuration, the detected pressure was about 53 mmHg. Note that this value is about the same as that detected by the sensor applied to the metal spatula (Fig. 7), but in this case without unwanted overpressure, such as that present at the edges of the metal spatula.

Finally, following deliquoration with a natural retraction of the brain, it is possible to remove a small chamber and replace it with a second larger chamber. This sequence is analogous to intermittent retraction (RosenØrn and Diemer, 1988). Once the desired dimensions are reached, it is possible to introduce the endoscope in a simple way and operate safely.

Because the tests were performed on a specimen, it is important to stress that they neglect the effects created by cerebral deliquoration during surgery. This allows for less spatulation on the brain as the parenchyma partially relaxes autonomously. However, the preliminary results of the present study are very promising for the further improvement of this innovative device with safer retraction and could be useful in developing new retraction knowledge and awareness. Furthermore, tests performed on specimens, as well as on a preclinical model made by UpSurgeOn S.r.l., showed no space perception problems. We plan to confirm the present data by simulating surgical approaches other than the pterional approach: tests on pigs are in progress. These preliminary tests have already confirmed that the surgeon's movements appear free and safe.

The need to use a spatula for cerebral retraction is common in all neurosurgical interventions. Surgeons unknowingly apply more pressure to the margins. Therefore, the possibility of acting safely while respecting the limit pressure forces is certainly an advantage.

We are preparing future studies to quantify brain retraction damage. Such studies can take place intraoperatively and in the postoperative phase as it is possible to monitor in real time the state of the brain parenchyma thanks to the transparency of our device. Monitoring can be performed in vivo by radiological imaging and on specimens by macroscopic observation of anatomical dissection. A fundamental aspect we are analysing is the alteration of cerebral tissue subjected to a retraction pressure: the device is being tested on animals from which we have taken samples of brain tissue subjected to different pressures, to quantify the brain damage caused by the device.

5 Conclusions

Thanks to technological developments, neurosurgical interventions are now able to treat even very complex pathologies in dangerous areas of the brain. Neurosurgical instruments have also evolved but the retractors are still harmful to the brain. Totally retractorless neurosurgery is arduous and truly difficult. Therefore, the development of new technological instruments to handle the brain more safely has become a necessity. Accordingly, in this paper, an innovative method of cerebral retraction is presented; through the use of a new CR, complications can be avoided, thanks to the absence of edges which, as shown by the FEM simulation, can cause excessively high pressures on the brain. Moreover, because of the ability to fix the desired diameter of the chamber, this retractor could form the basis of a new generation of tubular retractors. An endoscope can be used with the chamber: some tests performed on animals have confirmed that the surgeon's movements appear free and safe with our device. Finally, the promising results achieved by this new designed device will encourage further improvement for ensuring a better outcome free from severe complications of patients. Furthermore, the device has already been tested blindly by several neurosurgeons in comparison with other retraction instruments and has shown positive preliminary results.

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Author contributions

Designed the study: Elena ROCA and Giorgio RAMORINO; Analysed and interpreted the data: Elena ROCA, Giorgio RAMORINO, Anna GOBETTI, and Giovanna CORNACCHIA; Designed the figures: Elena ROCA, Giorgio RAMORINO, and Anna GOBETTI; Wrote and edited manuscript: Elena ROCA, Giorgio RAMORINO, Anna GOBETTI, Giovanna CORNACCHIA, Oscar VIVALDI, and Barbara BUFFOLI. All authors have read and approved the final manuscript, and therefore, have full access to all the data in the study and take responsibility for the integrity and security of the data.

Compliance with ethics guidelines

Elena ROCA, Anna GOBETTI, Giovanna CORNACCHIA, Oscar VIVALDI, Barbara BUFFOLI, and Giorgio RAMORINO declare that they have no conflict of interest.

This study was performed in accordance with the Declaration of Helsinki. The donor provided written informed consent before death for the body to use in medical education and research. The manuscript does not contain clinical studies or patient data.

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