

Novel pressure-sensing skin for detecting impending tissue damage during neuroendoscopy

Laboratory investigation

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Object. Endoscopy plays an increasingly important role in minimally invasive neurosurgery. Visual feedback from the endoscope tip helps the surgeon prevent unwanted tissue contact. However, critical feedback regarding tissue deformation and trauma from proximal endoscope components is currently unavailable. A system for force feedback along the endoscope length could provide significant clinical benefit by warning of impending damage.

The authors manufactured and tested a novel pressure-sensing polymer skin for use in pressure feedback during intracranial endoscopy.

Methods. A photolithography process on a silicon wafer was used to produce a pattern of 80-μm-tall extrusions to serve as a positive mold for the sensor array. A thin layer of polydimethylsiloxane polymer was molded onto these features. Demolding the polymer from the wafer and sealing with another polymer layer resulted in microchannels. These microchannels were filled with a conductive liquid metal and connected to recording hardware. Spiral channel patterns were designed to create a 3 × 3 array of pressure-sensor pads, which were wrapped around a standard neuroendoscope operating sheath. Pressure readings from the compressed sensor array were translated into a color-coded graphic user interface. Calibration experiments were conducted, and the sensor was evaluated through cortical compression tests on explanted ovine brain.

Results. The sensing endoscope operating sheath was successfully calibrated to detect and display pressures within a range consistent with normal and tissue-threatening compressions.

Conclusions. Force-feedback mechanisms for the neuroendoscopist are critically lacking with contemporary endoscopes. The authors designed a pressure-sensing skin technology for improved pressure feedback during endoscopy as a means for minimizing collateral tissue damage during endoscopy.
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KEY WORDS • endoscopy • haptics • flexible polymer • pressure sensor • retraction • technique

NEUROENDOSCOPY has come to play an increasingly important role in minimally invasive brain and spine surgery. The endoscopes used for such operations are often constructed from rigid metal tubes containing rod-lens devices or flexible optical fiber bundles that deliver light to and from the surgical site.⁵⁸ These visualization tools have introduced a number of key advantages to endoscopic surgery, including lessening collateral tissue trauma during the operative approach, increasing direct visualization of the surgical site through improved optics and light delivery, and providing the ability to navigate complex intracranial geometries that could not previously be accessed.¹⁵ Endoscopy has come to have an

increasingly central role in the treatment of intracranial pathologic conditions such as hydrocephalus,^{52–55} colloid cysts,¹⁵ pineal region tumors,³⁹ infectious intraventricular lesions (for example, neurocysticercosis),^{8,15} intraventricular hematomas,¹⁵ intraventricular tumors,^{24,25,27,34,40,42,46,50} and pituitary and skull base tumors.⁵⁸

Although endoscopy offers a considerable advantage by enabling the surgeon to see through narrow operative spaces directly to the surgical target site, endoscopes and introducer sheaths do not provide the surgeon the same visual and tactile feedback provided by equivalent open surgical procedures. The pivoting and lateral motions of the endoscope components during the operation do not

Abbreviations used in this paper: eGaN = eutectic gallium-indium; GUI = graphical user interface; PDMS = polydimethylsiloxane.

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This article contains some figures that are displayed in color online but in black-and-white in the print edition.

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easily enable the surgeon to detect the forces being exerted on surrounding structures. This lack of critical feedback to the surgeon can place delicate fiber tracts, cranial nerves, and adjacent brain parenchyma at risk for inadvertent injury from undetected compression or excessive application of force.

This principle can be illustrated with the increasingly common procedure used to treat noncommunicating hydrocephalus, endoscopic third ventriculostomy.^{4,12,14,18,28,31,32,36,49} During this procedure, an endoscope is passed through frontal lobe parenchyma, through the anatomically complex lateral and third ventricular spaces, to enable penetration of the floor of the third ventricle. If compression by the endoscope shaft goes undetected, delicate neural structures can be injured during endoscopic third ventriculostomy.^{11,12} Injured structures might be the oculomotor nerve (during penetration of the third ventricular floor), the fornix (during passage of the endoscope rod through the foramen of Monro), and/or the thalamus and midbrain (during canalization of the endoscope into the lateral ventricle or during manipulation of the endoscope shaft).^{11–13,21,22} An ability to monitor the pressures being applied along the length of the surgical instrument could provide critical feedback about impending collateral damage and enable the surgeon to avoid this damage.

Pressure sensors have long been used in neurosurgery and include intracranial pressure monitoring,³⁸ pressure-sensing intravascular catheters,⁵¹ and sensing brain retractors.^{1,2,3–7,20,29,37,47,57} However, consistent models of the association between focal brain pressure and tissue damage (mechanical, ischemic, or otherwise) have been difficult to develop in light of the numerous potential physiological and mechanical variables involved. Depending on the conditions of force loading and location within the central nervous system, the material properties of gray and white matter demonstrate significant differences in compressibility, nonlinear material behavior, hysteresis, and conditioning.^{43,44}

Several studies have helped parameterize the relationship between nonimpact focal parenchymal pressure and tissue damage. Hongo et al.²⁹ affixed a strain gauge-coupled flexible brain retractor to a self-retaining retractor system and measured pressures during a variety of vascular and tumor resection procedures conducted by an experienced neurosurgeon. Standard retractor pressures were found to be approximately 20 mm Hg during these procedures, without retractor-related cortical injury. Likewise, Rosenorn and Diemer⁴⁸ used a rat craniotomy model to apply lead weights at 20, 30, and 40 mm Hg with sustained pressure for 15 minutes under standard physiological conditions. Later histopathologic analysis of the cortical tissue revealed that cortical damage was minimal at 20 mm Hg of pressure, yet uniform infarction and tissue disruption to all cortical layers occurred in all rat brains tested at 40 mm Hg.

These pathophysiological studies of the pressure/damage relationship in brain parenchyma set the stage for developing a sensor technology capable of monitoring these pressures in real time during the course of a neurosurgical procedure. Applied in such a way as to transduce pressure along the length of the endoscope or introducer sheath, such sensors could provide immediate feedback to

the surgeon. We developed a novel pressure-sensing skin to provide pressure feedback during intracranial endoscopy. We illustrated its potential application by incorporating it onto a standard rigid endoscope introducer sheath, performing a series of calibration experiments, and then using the device to perform an ex vivo tissue compression validation test.

Engineering and Manufacturing of the Pressure-Sensing Skin

A variety of touch/pressure sensing techniques use a spatial grid of capacitive,²³ piezoresistive,³ or piezoelectric polymer⁴⁵ sensors capable of discerning the location and magnitude of an indentation force/pressure. However, recent advances in soft sensing have provided yet another option for distributed sensing. The technology is based on embedding microchannels filled with a conductive liquid in a thin polymer membrane.¹⁹ Measuring changes in conductive properties of the liquid as the channels are exposed to external forces enables precise determination of pressure. These skins mimic the mechanical characteristics of soft tissue, such as easy conformation to various geometries and stretchability.

The basic design concept for the creation of the pressure-sensitive skin was adapted from Kramer et al.^{33,41} and is illustrated in Fig. 1. First, a photolithography process was used to pattern 80-μm-tall extrusions on a silicon wafer, which served as the positive channel molds. Next, a thin layer of polydimethylsiloxane (PDMS), an inexpensive synthetic silicone, was molded onto these extrusions. This channel geometry is retained when this solidified PDMS layer is demolded. Finally, these channels were sealed with a flat-bottom PDMS layer. The resultant sealed channels were filled with a conductive liquid metal—eutectic gallium-indium (eGaIn) was used in these experiments—through a series of filling ports. The stability and lack of toxicity render PDMS an excellent biocompatible material. Although eGaIn was chosen for ease of initial prototyping, alternative biocompatible fluids, such as sodium chloride solutions and glycerol, are a subject of current study and could be easily substituted in such flexible polymer sensors.^{16,17,26,35,56} These conductive fluids remained sealed within the PDMS membrane.

The resistance of a conductive channel is inversely proportional to its cross-sectional area. As the channel is deformed by an external force F, its cross-sectional area is decreased, thus leading to increased measured channel resistance (Fig. 2). This increased resistance is correlated with the applied force magnitude, thus yielding the desired applied force sensing.

The need to sense the direction of the indentation force necessitates a distributed array of discrete sensor regions. Given that all embedded channels will be sensitive to the application of an external load, the portions of the channel designated to be individual sensors need to feature a geometry that maximizes the exposed channel surface area to the applied pressure. For this reason, our implementation of this sensing technology to neuroendoscopy featured sensing channels in the form of spirals (Fig. 1a). Each spiral featured a circular sensing area of 4 mm in diameter, with 3 sensors spanning a total length of 25

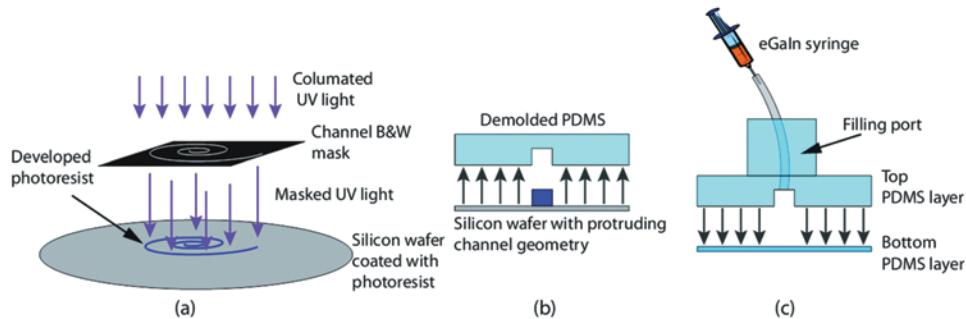


Fig. 1. Manufacturing steps for the soft sensing skin. **a:** A photolithography process is used to pattern 80- μm -tall extrusions on a silicon wafer coated with photoresist. Photoresist is a light-sensitive material that, after exposure to ultraviolet (UV) light, becomes insoluble to a developer solution. Only that portion of the silicon wafer under the custom-designed spiral pattern of the black and white (B&W) mask is exposed to the UV light. Treating the exposed wafer with the developer solution eliminates the nonexposed photoresist, leaving only the protruding spiral pattern. **b:** The polymer PDMS is poured over the silicon wafer with the protruding geometry, creating a spiral channel when the PDMS layer is demolded. **c:** An additional bottom layer of PDMS is added to seal the channel, and the channel is filled by injecting the conductive fluid eGaN through a filling port. Copyright Patrick J. Codd. Published with permission.

mm. The basic unit sensor design was then incorporated into a 3×3 array of pressure sensors (Fig. 3a). Insulated 43-gauge copper wires were inserted into the appropriate input and output channels of each pressure sensor array (Fig. 3b), and these wires were connected to the recording circuits. The sensing array was then wrapped and sealed around a polyimide plastic tube, 6.5 mm in diameter (American Durafilm Co., Inc.), serving as the backing layer that could easily be slipped on and off a standard 6.5-mm (13-mm working length) endoscope operating sheath (Karl Storz Neuro-Endoscopy, no. 28162BS) (Fig. 3c). This process resulted in 300- μm -thick transparent PDMS sheets with embedded channels sensitive to external pressures. The soft and flexible nature of these sensing materials likewise satisfied the need to minimize mechanical tissue trauma.

Custom signal conditioning circuitry coupled to a data acquisition board was built to achieve the conversion of a resistance change caused by microchannel compression to a voltage change that could be recorded by a data acquisition board. A current of 500 μA was applied to the sensor array. The voltage drop across each sensor, after

analog amplification of 100 times, was digitized by a data acquisition board (Measurement Computing, USB-1208ls). This gain value was chosen to achieve the desired sensitivity of pressure force range P between 0 and 30 mm Hg. A graphical user interface (GUI) developed in MATLAB (The MathWorks, Inc.) consisted of color encoding of the pressure load on each sensor. This color encoding ranged from yellow, indicating no load, to dark red, indicating an external pressure of 30 mm Hg or greater.

Sensor Calibration Experiments

For such an artificial sensing skin to be useful for the surgeon, 2 critical relationships are necessary: 1) the change in the measured sensor circuit resistance must be correlated with the applied pressure, and 2) the applied pressure must be related to nervous system injury to properly warn the surgeon of impending injury.

Calibration of the sensor array was performed by using the experimental apparatus shown in Fig. 4. The sensing array was slipped onto a 6.5-mm-diameter aluminum tube representing the endoscope operating sheath and

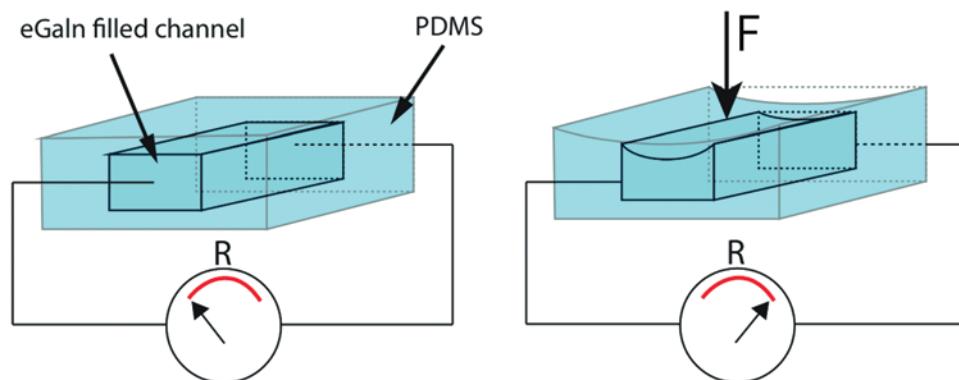


Fig. 2. Principle of operation of a soft eGaN microchannel pressure sensor. **Left:** The eGaN-filled channel is completely enclosed by the PDMS sheet. Wires introduced into both ends of the microchannel allow an electrical circuit to be created, with resistance (R) of this circuit measured. **Right:** Application of a force (F) causes microchannel deformation and concomitant increased resistance within the circuit. This increased resistance can be correlated with the magnitude of force applied. Copyright Patrick J. Codd. Published with permission.

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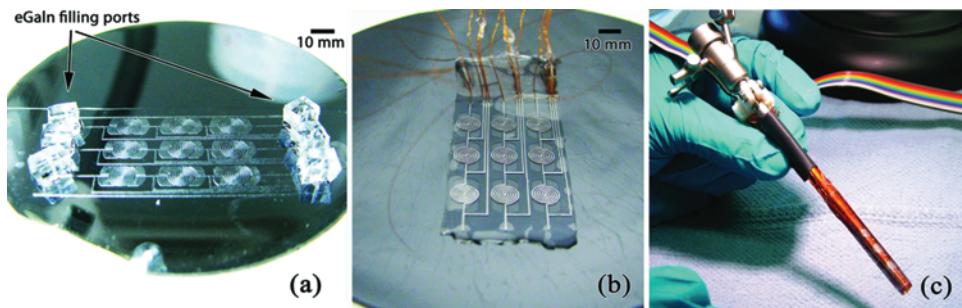


Fig. 3. Production of the pressure-sensing array for the endoscope operating sheath. **a:** The flat-channel geometry with fill ports before the demolding step (note the spiral microchannels arrayed in 3 parallel rows of 3 channels each). **b:** The microchannels have been filled with eGaN, and coated copper microwires have been inserted. **c:** The final flat-sensor array has been mounted on the endoscope operating sheath. The thin orange polyimide tubing on which the sensor array is mounted enables easy application and removal from the endoscope operating sheath. A heat-shrink polymer wrap (dark gray) binds the wires to the operating shaft before their collection into the cable leading to the data acquisition board (seen as *multicolored cable*).

mounted on a Newport manual z-axis stage. The sensor array was then brought into contact with an indentation surface shaped as a semicircle cutout, extruded to 5 mm. The indentation surface was molded from Mold Star 15 rubber (Smooth-On), featuring a hardness of 15 on the Shore durometer A scale approximating that of cortical tissue.³⁰ Furthermore, the semicircular shape ensures full and uniform contact of the sensing skin with the indentation surface, mimicking clinical contact with brain tissue. Simulation of lateral brain tissue deformation by the endoscope sheath was achieved by lowering the manual z-axis stage with the mounted sensor pad into contact with the testing surface.

The applied load was measured by a Scout Pro 200-g weight scale (OHAUS Corp.). Conversion of force to pres-

sure is achieved by assuming that the total force load is uniformly distributed at the area of contact, defined as follows:

$$A = \pi \times R \times L$$

where R (the radius of the introducer sheath) = 3.25 mm, and L (the length of the indentation surface) = 5 mm, thus yielding A (area of contact) = 51 mm². Hence, the contact pressure was calculated as $P = F/A$, where F is the weight measured with the scale. On the basis of previous observations about the pressure/tissue damage relationship,^{29,47,48} a limiting value of 30 mm Hg was targeted.

Individual sensor pads of the array were tested by using the calibration setup. Each sensor could be individually characterized to model its sensitivity to applied load via several indentation experiments (Fig. 4). Overall, each sensor features a linear dependence on the applied load; a sample indentation curve of Sensor 2 is shown in Fig. 5. The inverse correlation between Sensor 2, on which the load is placed, and Sensors 1 and 3 illustrates a negative effect of using a fluid metal as the conducting medium. Because these 3 channels are on a single eGaN circuit (Fig. 3b), the application of pressure on Sensor 2 microchannels forces the liquid metal into the remaining two sensors, 1 and 3, physically dilating them and, thus, causing a drop in resistivity and voltage. The negative voltage signals were ignored in the GUI because the tissue is assumed to not provide any adhesive forces.

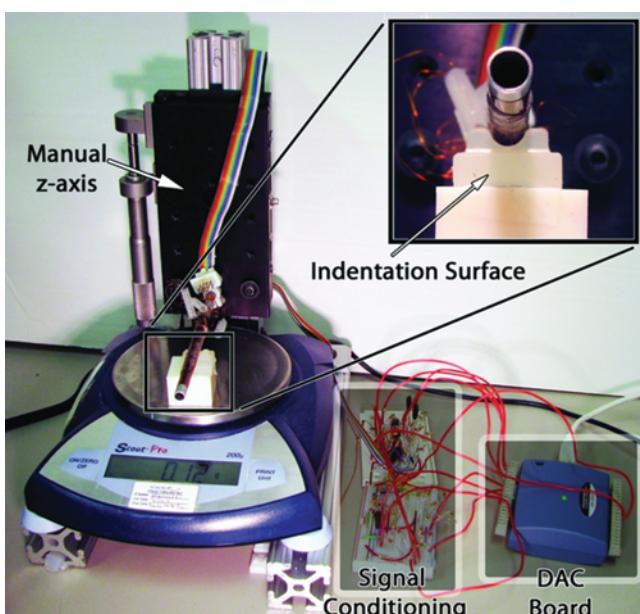


Fig. 4. Sensing skin calibration experimental setup. Each spiral sensor pad is sequentially lowered onto the indentation surface placed on a weight scale. Changes in the channel resistance are processed through analog signal conditioning and a data acquisition (DAC) board and recorded on an adjacent computer (not shown). Pressure can be derived through the assumption of uniform sensor contact and the measured weight and correlated with the recorded signal data.

Ex Vivo Tissue Validation Test

With the pressure sensor array calibrated, it was then possible to perform an initial correlation between pressure data recorded in real time from the sensing skin with visual feedback regarding brain parenchyma interactions. Following institutional protocols for the handling of animal tissues, an unfixed adult sheep brain was explanted after an unrelated terminal procedure. To preserve the integrity of both hemispheres, excessive tissue handling was avoided. The brain was placed into the testing apparatus, and the tissue was kept moist with normal saline.

To validate the pressure-sensor calibration relative to tolerable tissue deformations, we conducted 2 experiments. The first was a cortical depression test (Fig. 6) in

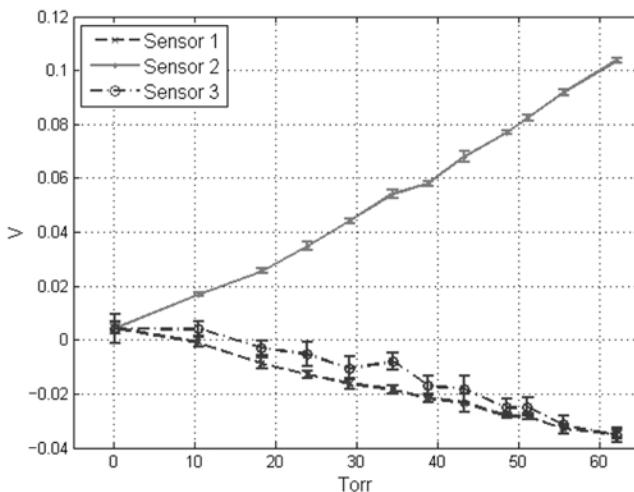


Fig. 5. Sensor array characterization curves illustrating mean voltage output (V) of Sensors 1–3 as a function of an indentation force applied on Sensor 2 (measured in torrs). The single standard deviation error bars at each point are calculated from a sample pool of 100 voltage readings.

which the endoscope operating sheath, bearing the calibrated 3×3 sensor array, was manually applied to the cortical surface with gradually increasing pressure. Using the previously described safe cortical pressure data as a calibration guide, we programmed the color-coded GUI so that the darkest red warning indication would be displayed when the pressure reached 30 mm Hg or greater. In this example (Fig. 6), 2 of the 3 sensors of the row were engaged with the cortical surface and transmitted contact information. The sensor consistently conveyed such contact information during repeated applications of the sensing operating sheath, providing intuitive color-coded feedback on the severity of the applied force.

The second test was a tissue interaction test, in which the endoscope operating sheath, bearing the calibrated sensing skin, was introduced roughly perpendicular through the brain surface to simulate a transcortical endoscopic trajectory. Again, gradual application of lateral pressure was manually applied while recording the pressure data and displaying it via the MATLAB GUI. A selected example of a single sensing pad engaged to the parenchyma is illustrated in Fig. 7. The threshold for the darkest red display warning (see graduated color scale bar in Figs. 6 and 7) was again set to occur when pressures reached 30 mm Hg or greater.

A comparison was thus possible between the visually observed magnitude of cortical deformation (as is often the current method of feedback available to the surgeon) and the quantitative measurements of pressure derived from the sensing sheath. In the cortical depression and the transcortical trajectory assessments, the red warning level was triggered at tissue deformations that would be worrisome for parenchymal damage.

Discussion

When endoscopes are used near delicate neural structures, or even when they pass through parenchyma, as with

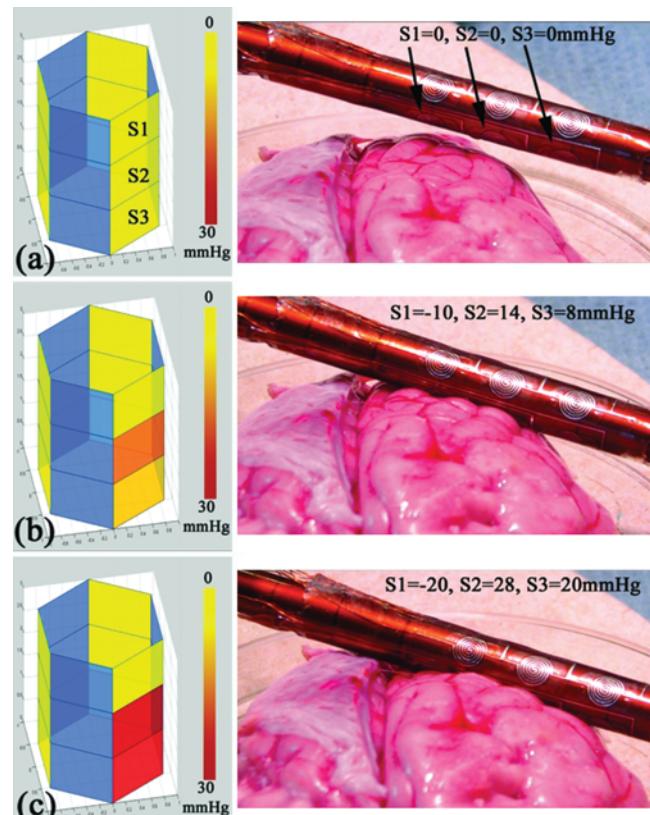


Fig. 6. Cortical depression test conducted by using the sensing endoscope operating sheath. The left panels (a–c) show the GUI. Each yellow rectangle represents a single sensor pad of the 9-sensor array in its resting state. As increasing force is applied to 2 contact pads on the cortical surface (S1–S3), the graded color proportionally transitions to red, which warns when the safety threshold of 30 mm Hg is reached. The mean values of the sensed external pressure read by each sensor are overlaid on the photos right.

intraventricular endoscopy, the ability to prevent unwanted pressure on adjacent structures is imperative for minimizing collateral tissue injury. In contemporary neuroendoscopy, these structures are not easily visualized or monitored by the surgeon during the course of a procedure. As neuroendoscopic procedures take on an ever-growing role in cranial surgery, methods for providing critical feedback about impending collateral damage along the entire length of the surgical instrument or endoscope are fundamentally necessary.

We developed and tested a novel pressure-sensing polymer skin that provides real-time pressure feedback during neuroendoscopy. Although the field of soft sensors has seen numerous recent technological advances and applications,^{3,33,41} to our knowledge, our work is the first to apply this promising technology to neurosurgery as a way to provide feedback to the surgeon. In this initial prototype, we chose to create a sensing skin capable of monitoring real-time pressure with a commonly used rigid endoscope operating sheath. However, the sensor array design can be customized and optimized according to particular surgical needs. Likewise, the thin, flexible nature of the PDMS material opens avenues for molding

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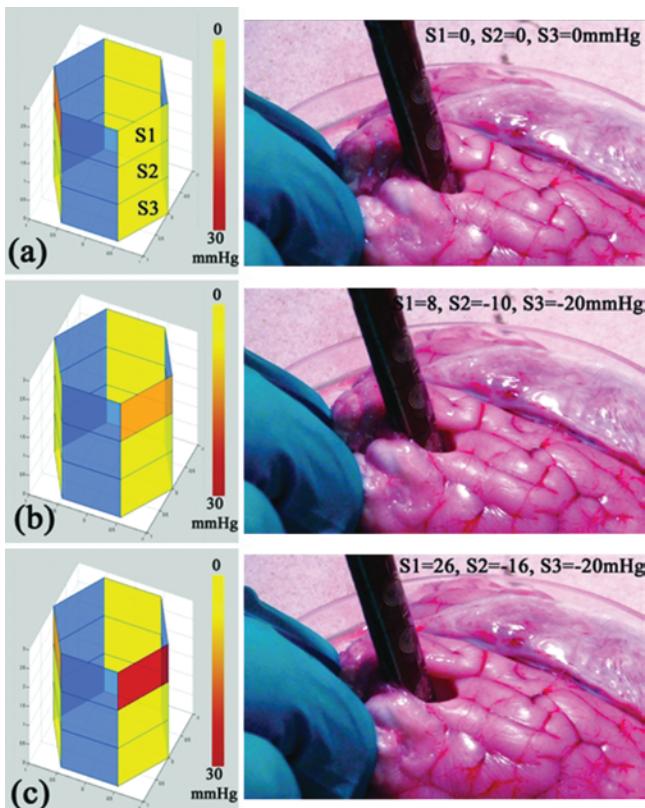


Fig. 7. Transcortical introduction of the sensing operating sheath with lateral motion testing. For demonstrative purposes, a single sensor, S1, is examined at increasing degrees of lateral displacement (a–c). As in Fig. 6, the darkest red warning threshold is again reached with applied force of 30 mm Hg.

this sensing skin around complex surfaces with minimal increase in instrument diameter or profile.

We have described this technology in the context of endoscopic third ventriculostomy as a familiar representative example of how this flexible sensing technology might be applied to improve patient safety. The applicability of flexible pressure-sensing skin need not be limited to a specific endoscopic procedure or to a specific endoscopic instrument. The adaptability of design and the flexibility of the material enable it to be attached to the entire length of endoscopic instruments, scopes, and introducer sheaths, flexible endoscopes, and even to standard open microsurgical equipment including brain retractor blades and microsurgical instruments. In fact, reduction of this sensing-skin concept to point-pressure measurements has already been developed to enable recording of tip force and contact angles, which could be used for force sensing at the tip of endoscope instruments or standard microsurgical dissection tools.⁹

This study represents proof of concept for this technology, and our initial characterization highlights several limitations that offer directions for future work. The most important future modification will be introduction of biocompatible alternatives to eGaIn. Although the optimal substitute is a topic of current study, we have recently demonstrated pressure sensors that use sodium chloride-saturated glycerine.²⁶ Additional factors such as the size

of the pressure sensor pad, the number of sensors per unit of sensing skin, and the sensitivity of the recording equipment provide avenues for iterative design that should be performed according to the clinical requirements described below. Improvements in each will augment device sensitivity and usability in a clinical setting. A pressure sensor array at the tip of the endoscope sheath was chosen to highlight the ability for the technology to transduce tissue-sensor interaction in the general setting of parenchymal contact. Future experiments to optimize sensor distribution and sensitivity will include incorporation of cranial models (including skull and intraventricular anatomy) to simulate the pivoting constraints of bur hole entry to more precisely reflect the intraoperative environment.

The relationship between nonimpact focal parenchymal pressure and tissue damage also merits careful consideration. This relationship is inherently difficult to establish because the mechanical properties of neurological tissue vary in compressibility, conditioning, and hysteresis, depending on the brain region and conditions of loading.^{43,44} Likewise, establishing which applied pressures actually result in permanent mechanical or physiological damage is difficult to quantify. However, several histopathologic studies on nonimpact focal parenchymal pressures have enabled useful approximations of this pressure/damage relationship,^{29,47,48} even in the setting of such diverse variables. We have used these approximations to establish the pressure/damage parameters, applying a pressure cutoff of 30 mm Hg to a given sensor pad as the darkest red danger threshold in the color-coded GUI. Although doing so provides a usable first approximation of tolerable manipulation of the brain parenchyma as might be encountered during endoscopic procedures, further histological studies are clearly warranted to objectively classify the range of tolerable deformations for superficial cortical structures, deep structures, and fiber tracts. To our knowledge, a systematic review of collateral tissue damage resulting from endoscope manipulation in the brain has yet to be performed. Such adaptable pressure-sensing skins could provide the research tool by which such studies could be systematically performed.

The modality of feedback is likewise open for exploration. We chose color-coded visual cues to provide a graded feedback proportional to the recorded pressures. With computer-augmented surgical devices and robotic surgical systems, using feedback modalities such as audition or haptics can reduce the cognitive load on the clinician and improve performance by uncluttering an already busy assortment of visual cues.^{10,59} We anticipate that the use of auditory and/or haptic feedback could provide the pressure information to the operator in an ergonomic, real-time manner, and we intend to explore these forms of feedback in future prototypes of the system.

Practical requirements for viability of this technique within the operating room will need to be considered. These include methods of sterilization while maintaining functionality of the microchannel circuitry and compact packaging of the sensory array and associated wiring to minimize crowding of the surgeon's workspace and operative corridor. It is envisioned that these sensing skins could provide single-use device augmentation in which the appropriate sensing skin could be applied to endo-

scope sheaths, rigid and flexible endoscopes, or other neurosurgical instrumentation. Alternatively, gas sterilization methods that preserve the polymer architecture might enable reusable designs. Efforts to explore these avenues are underway. Although explanted brain tissue was used for validation testing in these studies, live animal testing will ultimately be needed to assess the utility of this technology *in vivo* before integrating it into the human operating room.

Conclusions

As endoscopic and minimally invasive approaches become increasingly common in neurosurgery, the operative corridors become narrower, and incomplete visualization of collateral tissues during surgical approaches can place important structures at risk. Thus, methods for providing haptic feedback to the surgeon and minimizing the risk for inadvertent harm to the patient have an increasingly vital role. We have presented the initial design, manufacture, and characterization of a novel sensing-skin technology for use in providing feedback to the surgeon during neuroendoscopic procedures. Although further work will be critical for improving sensitivity, accuracy, and integration in the human operating room, this work represents a major first step toward smarter surgical instrumentation and safer minimally invasive procedures.

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Disclosure

The authors report no conflicts of interest concerning the materials or methods used in this study or the findings specified in this paper. The authors have no personal or financial interests in any of the materials or devices described in this article.

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