A Handheld Robot for Endoscopic Endonasal Skull Base Surgery: Updated Preclinical Validation Study (IDEAL Stage 0)

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Abstract

Background and Objectives Endoscopic endonasal surgery (EES) has become increasingly popular, yet anatomical constraints posed by the nose and limitations of nonarticulated instruments render EES technically challenging, with a steep associated learning curve. Therefore, we developed a handheld robot to enhance dexterity in endoscopic neurosurgical procedures. A previous trial of the robot demonstrated its potential advantages in endoscopic neurosurgery but also the need for improvements. In this study, we assess the feasibility, acceptability, and comparative performance of the updated robotic prototype (version 0.2) against standard instruments in a preclinical phantom and cadaveric trial.

Methods Ethical approval was received. Participants were stratified according to their neurosurgical experience. In the phantom study, a randomized crossover design compared the robot against standard instruments at a phantom tumor resection task. Statistical analysis was performed using Mann–Whitney U tests and paired *t*-tests. In the cadaver-based user study, participants evaluated the device's functional domains through a qualitative interview design.

Results In the phantom study, the device demonstrated a learning curve: initial resection attempts favored the traditional instrument (84% vs. 59%, $p = 0.055$), but parity was achieved by the fifth attempt (80% vs. 83%, $p = 0.76$). Acceptability was evident, as most clinicians (7/8) preferred the robot for its superior range, ergonomics, and precision. Also, the robot exhibited a diminished cognitive workload. The cadaveric

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study underscored the robot's clinical feasibility, through sufficient workspace reach and force delivery.

Conclusion: Overall, our robot demonstrates promising acceptability and feasibility for endoscopic neurosurgery, yet further iterative developments are required before proceeding to in-human clinical trials.

Introduction

Endoscopic endonasal surgery (EES) offers several advantages over traditional transcranial approaches when treating skull base pathologies, including reduced exposure and neural tissue manipulation.[1–3] Indeed, the endoscopic transsphenoidal approach (eTSA) has become an increasingly common approach to the sella, and the expanded endoscopic endonasal approach (EEEA) has extended the surgical reach beyond the sellar region to include the anterior cranial fossa, parasellar region, clival region, and craniovertebral junction.[1–3] Nevertheless, EES is challenging due to the anatomical constraints enforced by the long, narrow nasal corridors, which impose a fulcrum effect on surgical instruments.[4] Additionally, current surgical instruments have a limited ability for tissue manipulation due to their lack of articulation.[5] Consequently, EES has a steep learning curve.[5]

To overcome these challenges, we have developed a handheld robot consisting of a miniaturized, articulated end-effector coupled with an ergonomic controller designed to offer an expanded workspace and greater dexterity in endoscopic neurosurgery. Previously, the device was found to improve maneuverability, was deemed easy and comfortable to use, and was preferred over conventional endoscopic instruments when evaluated by neurosurgeons with prior experience with EES.[6]

However, certain limitations were identified, including insufficient force delivery during robotic joint actuation, challenges with precision, limited diagonal workspace reachability, and tissue entrapment within the joints. Additionally, the joystick was deemed to lack appropriate sensitivity.[6] Therefore, the robot has undergone significant design and manufacturing updates, including larger motors, end effector re-design, and more sophisticated control software.

In this study, we present an evaluation of the updated handheld robot (version 0.2). First, we perform a preclinical randomized cross-over study to compare the robot against standard endoscopic instruments in a phantom pituitary tumor resection task. Second, we conduct an iterated cadaveric study to evaluate surgeon perceptions of the engineering updates.

Methods

Device Development

A detailed description of the development and re-design of the robot has been published separately.[6,7] In brief, the handheld robotic system is composed of an ergonomically designed, handheld controller with a rotating joystick body that can be placed at the position most comfortable for the user, its accompanying control box, and articulated 2 or 3 degrees-of-freedom end-effectors utilizing a wide range of interchangeable articulated instruments at its distal end. For this study, only the curette end-effector was used, as the device was compared with a standard curette instrument. Since the previous study, key updates include integrating larger motors, an end-effector re-design to allow for a wider effective workspace, incorporation of closed-loop control both in position and velocity modes, parameter tuning, and return-to-neutral functionality. The handheld device is shown in ►**Fig. 1**.

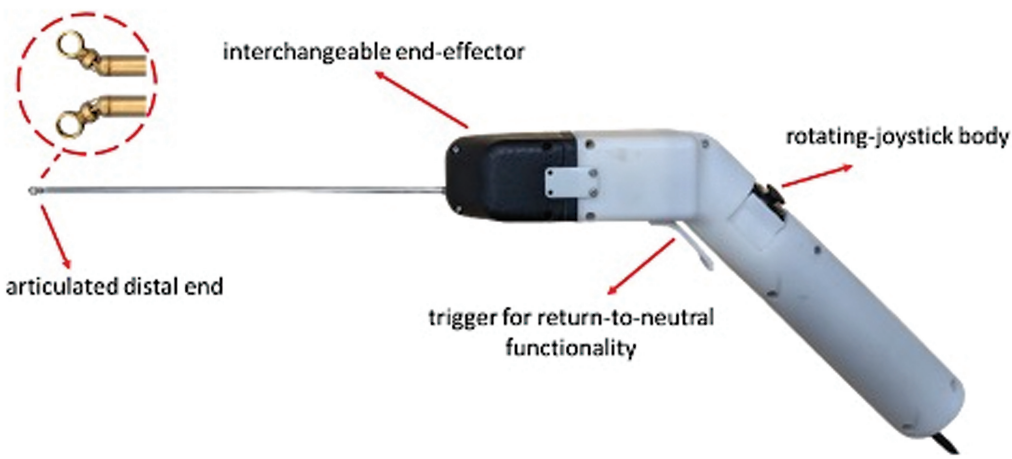

Fig. 1 Depicts the handheld robot with its articulated distal end, interchangeable end-effector, trigger and rotating-joystick body.

Participant Recruitment

Participants were recruited from a single university teaching hospital and were defined as (1) experts if they had completed neurosurgical training, (2) intermediates if they were neurosurgical registrars (residents) with experience in pituitary surgery, and (3) novices if they did not meet either of the previous criteria. Demographic data, including the stage of training, sex, and handedness, were recorded.

Phantom-Based Comparative Study

Study Design

The study was approved by the local ethics committee (reference: 17819/001). The phantom study compared the robot against standard endoscopic instruments in a pituitary tumor resection task. Eight participants were recruited. Due to pragmatic constraints in trial design, no formal power calculation was performed. A randomized crossover study was conducted using a validated phantom model for the eTSA (UpSurgeOn Transsphenoidal [TNS] Box).[8] The TNS Box was prepared by creating a surgical corridor such that the tumor was accessible. Participants were tasked with performing a tumor resection after a short standardized introduction to the robot and standard instrument.[9] This was performed using either the standard instrument (a bayonet-shaped, 45° angled ring curette, model: FA061R, BBraun, Germany) or the robot. Participants were given 3 minutes for tumor resection. The end-effector for the robot consisted of a ring curette with similar dimensions to the standard instrument. Participants performed the resection task five times using each instrument. The tumor and dura were replaced for each iteration, but the rest of the model remained the same. Tumors were weighed before and after the resection task to calculate the extent of resection (EOR).

Following the resection tasks, participants completed a validated, surgery-specific task load index (SURG-TLX[10]), which prompted them to consider the extent to which they experienced various intraoperative workload domains. Workload domains included mental, physical and temporal demands, task complexity, situational stress, and distractions. Participants completed weighted ratings of each subdomain, which were aggregated to produce a total workload score.[10]

Finally, participants completed a post-task questionnaire to score each instrument regarding ease of use, comfort, precision, and integrity. The scores ranged from 1 to 5 points (1 = poor, 5 = excellent). The overall preferred instrument was also assessed.

Outcomes

The primary outcome was the median EOR achieved on the final (fifth) attempt. The difference between the first and final attempt was used as the comparative metric to account for potential learning curve effects. Secondary outcomes included the median EOR on the first attempt, the composite SURG-TLX workload scores, and post-task questionnaire outcomes.

Statistical Analysis

R Studio (2022.07.2) and Excel (Microsoft, version 16.6.1) were used for data analysis and data representation. Outcome measures, including the EOR and SURG-TLX, were expressed as median (interquartile range [IQR]) and statistical differences were assessed using nonparametric tests (paired, Mann–Whitney U-test). For parametric data distributions (e.g., post-task questionnaire), paired *t*-tests were performed. Categorical variables, such as the favored instrument, were evaluated using a chi-squared test. $p < 0.05$ was deemed statistically significant.

Cadaver-Based User Study

Cadavers were used according to the local anatomical board's ethical requirements. The objective of the cadaver-based study was to qualitatively evaluate the feasibility and acceptability of the device through the exploration of surgeon opinions regarding domains pertaining to the robot's design updates. One fresh and frozen cadaver was obtained for the study, serving as the subject for all participants in the surgical tasks. The eTSA, including the durotomy, was performed pre-task by the expert neurosurgeon.[9] Following this, participants explored various functional domains of the device by completing simple tasks, detailed in ►**Table 1**. Participants performed each task using two modes of end-effector control: position mode and velocity mode. In position mode, the end-effector follows the position of the joystick, meaning when the joystick is released, the end-effector is at a neutral position. In velocity mode, the joystick determines the desired change in position of the end-effector, meaning when the joystick is released, the end-effector maintains its position. Participants were interviewed while performing each task to gather their opinions with respect to the device's: (1) reachable workspace, (2) precision, (3) force-delivery, (4) ease-of-use, (5) structural integrity,

Table 1 Cadaveric tasks

Task
Using the joystick, explore the vertical, horizontal, and diagonal movement capabilities of the robotic end effector.
On the video display of the endoscope, the assessor will now ask you to touch 4 points inside the sphenoid sinus.
Place the end effector against the mucosa of the sphenoid sinus. Then, using the joystick, assess the applicable force at the hinged end-effector moving the sphenoid sinus mucosa and pituitary gland.
The surgical tasks are now complete, you may interact with the tissue environment as you wish.

(6) drawbacks, and (7) benefits compared to standard instruments. Their answers underwent a reflexive, thematic analysis.[11,12] All interview questions can be found in ►**Supplementary Table S1**.

Results

Phantom Study

Demographics

Participants included six males and two females. There were two experts, two intermediate, and four novice participants, of which seven were right-handed and one was left-handed.

Extent of Resection

On the first attempt, participants using the standard instrument and robot achieved a median EOR of 84% (IQR: 65–91%) and 58.6% (IQR: 52–77%), respectively ($p = 0.055$). On the final attempt, the median EOR with the standard instrument and robot were 80% (IQR: 70–89%) and 83% (IQR: 61–94%), respectively ($p = 0.76$). The EOR improved across attempts with the robot ($p = 0.38$) and decreased with the standard instrument ($p = 0.95$) (►**Fig. 2**).

Experts and intermediates outperformed novices on the first resection attempt using both the standard instrument (87% vs. 76%, $p = 0.25$) and the robot (71% vs. 55% $p = 0.25$). Novices achieved a first-attempt EOR of 76% (IQR: 60–86%) with the standard instrument and 55% (IQR: 52–91%) with the robot ($p = 0.62$) (►**Fig. 3**). On their final attempt, novices resected 80% (IQR: 70–84%) with the standard instrument and 83% (IQR: 64–91%) with the robot ($p = 1.0$). Intermediate and expert surgeons achieved a greater first attempt EOR with the standard instrument (87%, IQR: 77–92%) compared to the robot (71%, IQR: 56–85%, $p = 0.12$). On the last attempt, intermediates and experts achieved an EOR of 80% (IQR: 70–91%) with the standard instrument and 80% (IQR: 61–94%) with the robot ($p = 0.88$).

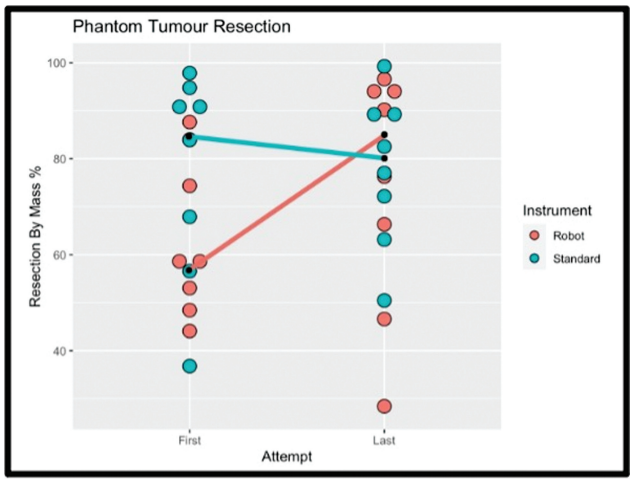

Fig. 2 Graph displaying the extent of phantom tumor resection achieved with the standard endoscopic instrument versus the handheld robot. The black circles signify median values for the respective instruments.

Fig. 3 Graph displaying the extent of phantom tumor resection achieved with the standard instrument versus the robot. Grouped by level of experience. The black circles signify median values for the respective instruments.

SURG-TLX Outcomes

Compared to the standard instrument, the robot was associated with a lower mean total workload score (standard =156, robot =118, $p = 0.006$). Considering subdomains, the robot was associated with a statistically significant reduction in perceived physical demands (robot = 5.4, standard instrument = 42, $p = 0.03$). Otherwise, subdomain differences were insignificant.

Post-task Questionnaire

►**Fig. 4** depicts the questionnaire results. All but one participant (7/8) favored the robot over the standard instrument overall ($p = 0.0027$). The reported robotic benefits included that it had a "better range of movement," "required fewer wrist movements," "was more comfortable," and "more precise." Reported drawbacks of the robot included that it was "uncomfortable to hold the thumb on the joystick," "(it) clashed with the endoscope," "would benefit from a longer curette," and required "haptic feedback."

Cadaveric Study

Demographics

Participants included one expert, one intermediate, and four novices. Two participants were female, and four were male. Five were right-handed, and one was left-handed.

Qualitative Outcomes

►**Fig. 5** depicts the robotic manipulation of the cadaveric tissue. All surgeons ($n = 6/6$) found the range of movement of the robot sufficient in all directional planes, including the diagonal movements, which were deemed to be insufficient in the previous device prototype.[6] One expert participant highlighted that "this feature could reduce the amount of instrument changes performed during an operation." All surgeons found the end-effector capable of applying sufficient forces at a predefined angle and during movement. Specifically, the expert neurosurgeon commented that the device was

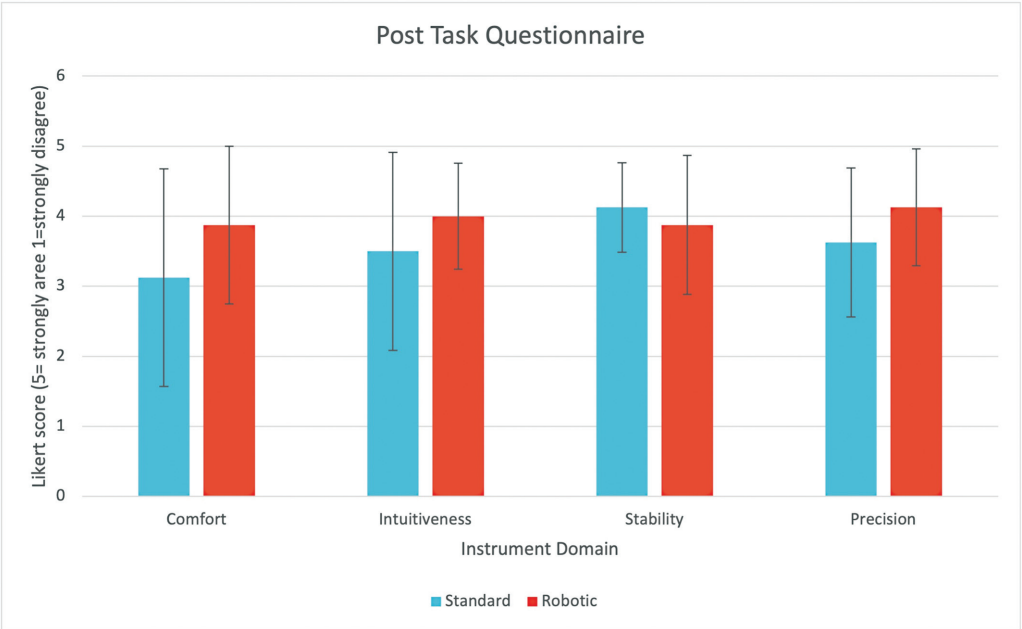

Fig. 4 Bar chart displaying the user ratings of instruments across four domains.

"more than capable" while another participant highlighted the device was "great for soft tissue manipulation" and that it could "even be used to scrape bone." Additionally, all participants found the instrument easy to use. Finally, when asked to pick a preferred end-effector control mode (i.e., position or velocity mode), participants found the modes equally capable across domains, including articulation, ease of use, precision, and force delivery.

Limitations of the robot were also highlighted by participants. First, the device handle was observed to occasionally clash with the endoscope, disturbing the operative workflow. Also, the lack of end-effector variety was highlighted. Additionally, the end-effector showcased minor structural damage during the last attempt by the last participant, suggesting the need for reinforcements. Finally, careful examination of the end-effector actuation suggests the presence of mechanical backlash.

Discussion

Principal Findings

In this study, we present an updated prototype (version 0.2) for the first-of-its-kind handheld robot designed for endoscopic neurosurgery. We compared the robot against standard instruments through a high-fidelity phantom study and established clinician perspectives of the engineering updates through a cadaver-based user study. The robot showed noninferior effectiveness and superior perceived workload whilst offering other potential advantages. Additionally, we identified domains for further iterative developments ahead

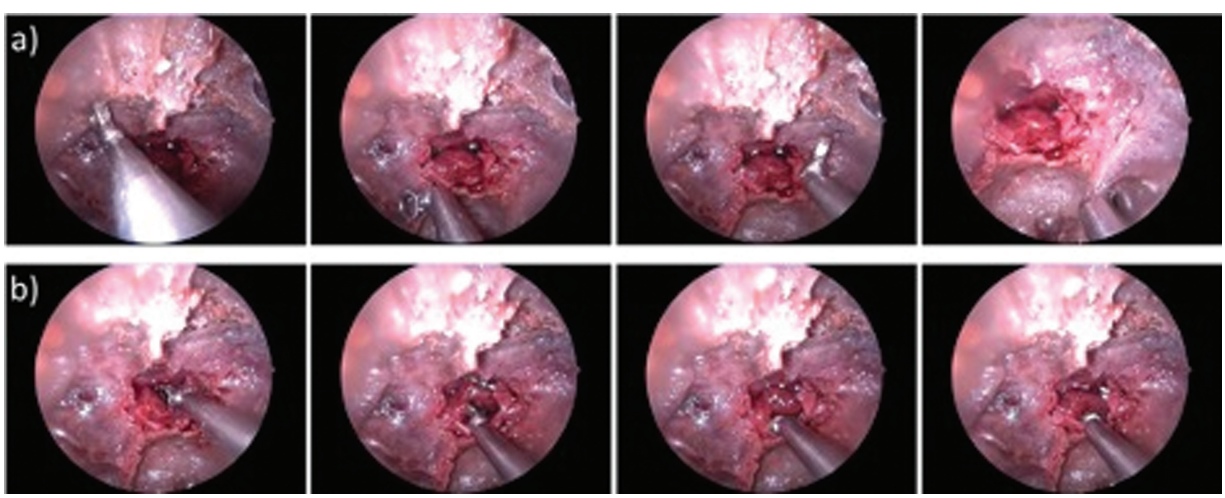

Fig. 5 The articulated end-effector inside the cadaveric specimen (**a**) actuated in different angles to test reachability and (**b**) interacting with soft tissue to test force-delivery.

of creating a prototype ready for a first-in-human assessment.

In the phantom study, we observed a learning curve effect, as the robot was inferior to the standard instrument on the first attempt at tumor resection (84% vs. 59%, $p = 0.055$) but equivalent on the fifth attempt (80% vs. 83%, $p = 0.76$). These learning curves will be used to guide clinician training with the robot prior to future clinical trials. Separately, participants scored the robot higher in terms of range of movement, ergonomic manipulation, comfort, ease of use, and precision. Indeed, the robot was associated with a lower total cognitive workload ($p = 0.003$), which may explain why users demonstrated a significant improvement with successive resection attempts using the robot, unlike with the standard instrument, with which resection outcomes decreased slightly. Overall, the robot was the favored instrument by 7/8 participants ($p = 0.0021$), implying clinician usability, a critical factor in the evaluation of early-stage medical devices, as outlined by the IDEAL-D framework.[13]

In the cadaver-based user study, participants expressed that in the context of the eTSA, the device achieved a sufficient range of movement in all directional planes and applied an appropriate amount of force with its end effector. Additionally, the expert surgeon highlighted that due to the expanded robotic workspace, one could envision that the device would reduce the number of instruments used intraoperatively. Such effects may improve operative workflow efficiency and thus reduce operative times. Overall, despite the need for further iterative developments, the device demonstrated clinical feasibility and user acceptability.

There were also drawbacks identified with the current device prototype, which are to be addressed in future iterations. The device's end effector experienced minor structural damage during the cadaveric study, indicating a need for a reinforced design. Furthermore, the larger size of the robotic handle resulted in clashes with the endoscope, which may limit the device's applicability to mono-nostril approaches.

Comparison with the Literature

Despite significant advances made in robotic-assisted surgery, the translation of such systems into endonasal skull-base surgery has been slow.[14] While studies have demonstrated the feasibility of robotic endoscope holders,[14] the only robot capable of tissue manipulation that has undergone clinical trials for skull-base surgery is the DaVinci system (Intuitive, Surgical).[15,16] However, the Da Vinci was built for general surgery and thus faces challenges related to its instruments' size, operating room footprint, and lack of dedicated tools (e.g., drills) when deployed for pituitary surgery.[15,16] Indeed, the DaVinci cannot be inserted through the nose and thus must currently rely on transoral approaches to the sella.[14]

Examples of robots purpose-built for endoscopic skull base surgery can be found in the preclinical stage of translation, in which continuum robots are popular. Such teleoperated "flexible robots" consist of thin, flexible, tubular shafts with interchangeable end-effectors capable of tissue manipulation.[17] Continuum robotic shafts may consist of pre-curved, concentric, tubular segments (controlled through the telescoped elongation and axial rotation)[18,19] or nitinol tubes that can be flexibly adjusted.[20] To date, preclinical studies have validated some of these designs in phantom tumor resection tasks conducted by a single expert.[18] However, continuum robots present their own issues related to sterilizability, controllability, and the need for a support base, which may limit distal-end dexterity and force delivery.[17,21] Handheld robots bypass many of these challenges.

In our study, we present the first-of-its-kind, preclinical, handheld robot for endoscopic skull base surgery, which offers several advantages over the aforementioned teleoperated alternatives. First, handheld robots do not require a support structure or base, reducing surgical workflow disruption. This "easy" integration into the operative workflow may have a profound effect on the human factors associated with robotic-assisted surgery, as avoiding the physical separation of the surgeon from the surgical team (as in teleoperated systems) reduces the demand for verbal communication, cited as the most common cause of procedural error and surgical injury.[22–26] Second, the robot has a smaller footprint, which can reduce purchasing and maintenance costs. Finally, it has a small and lightweight design, resembling typical surgical instruments and thus can more easily be adopted in procedures where frequent tool changes are required, such as the EEEA.[27]

Since the first study describing our handheld device, engineering updates have addressed previous limitations related to diagonal workspace reachability and effector force-delivery. As demonstrated in our cadaver-based surgeon interviews and phantom resection tasks, our device is easy to use and clinically feasible. Indeed, surgeons across the continuum of surgical experience preferred the handheld robot over conventional tools.

Strengths and Limitations

Our study's strengths relate to the surgically relevant context in which the engineering updates were evaluated. In the phantom study, experts outperformed novices at the surgical resection task, implying the TNS model was reliably able to distinguish surgical performance (whether due to skill or instrument differences). Also, the cadaveric study enabled users to explore the device's functional domains in the highest fidelity setting possible. This suggests the benefits observed in our study will be replicated in future in-human evaluations.

Our study also has limitations. First, the pragmatic constraints in the number of recruited participants limited our results' statistical significance. Additionally, the number of resection attempts in the phantom study was low; hence it is unknown if the improved resection performance observed with the robot would have continued with further practice. Separately, due to the lack of realism in the resection task, some participants used unrealistic gestures, such as squeezing the tumor out of the synthetic dura. Finally, participants were not blinded to the trial's intent, which may have biased subjective interviews.

Conclusion

This study presents an updated prototype for the first-of-its-kind handheld robot designed for endoscopic neurosurgery. The device demonstrates its clinical feasibility and user-acceptability when compared to standard endoscopic instruments. Additionally, interviewed neurosurgeons reported sufficient workspace reachability, force-delivering capabilities, and precision. Overall, we demonstrate that the device is comfortable, easy to use, precise and clinically effective, yet has scope for further iterative improvements.

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Conflict of Interest
None declared.

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