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High-Accuracy Augmented Reality Guidance for Intracranial Drain Placement Using a Standalone Head-Worn Navigation System: First-in-Human Results

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BACKGROUND AND OBJECTIVES: External ventricular drain (EVD) placement is often performed freehand, a technique subpar to accurate yet impractical image-guided methods, yielding optimal placement in only 70%. The aim of this study was to address shortcomings in EVD placement and image guidance technologies by implementing high-accuracy augmented reality (AR) guidance.

METHODS: We conducted a prospective clinical pilot study to assess feasibility, safety, and clinical performance of EVD placement using a standalone AR headset equipped with high-accuracy inside-out infrared tracking and software addressing EVD placement. Placement quality was reported using a newly defined extended modified Kakarla scale, and dichotomized into clinically relevant outcome parameters. Results were compared with a nonconcurrent freehand control group using one-sided Fisher exact tests.

RESULTS: Eleven AR-guided EVD placements were performed, achieving functional placement in all cases on the first attempt, vs 7 (64%) in the control group ($P = .045$); successful placement in 9 (82%) vs 5 (45%); optimal in 8 (73%) vs 3 (27%) ($P = .043$); suboptimal in 2 (18%) vs 5 (45%); and failed in 0 vs 1 (9%). No AR-guided placements required revision, whereas the freehand group had a 36% reintervention rate ($P = .045$). Procedure-related complications occurred in 2 AR-guided cases (18%), vs 5 (45%) freehand (all post-reintervention).

CONCLUSION: This study presents the first clinical use case of EVD placement using high-accuracy AR guidance contained in a standalone head-worn navigation system. Safe and reliable outcomes using a validated pipeline were demonstrated, eliminating stick-and-poke attempts and resulting in improved quality, increased single attempt success rates, and reduced revision and complication rates. Based on these results, a multicenter randomized controlled trial will be initiated.

KEY WORDS: Augmented reality, Neuronavigation, Computer-assisted surgery, Ventricular drain placement, Ventriculostomy, External ventricular drain placement

ABBREVIATIONS: AR, augmented reality; **emKS,** extended modified Kakarla scale; **EVD,** external ventricular drain; **IC,** informed consent; **IPH,** intraparenchymal hemorrhage.

Supplemental digital content is available for this article at neurosurgery-online.com.

External ventricular drain (EVD) placement is often performed freehand, relying on computed tomography (CT) imaging in conjunction with literature-defined anatomical landmarks, which are not tailored to individual patients.[1] Given the absence of patient-specific guidelines, the literature dictates their use even in the presence of anatomy-altering pathology.[2] Consequently, the freehand technique may not yield the best outcome in such cases (Figure 1)[3,4] and has been identified as primary risk factor of improper placement when compared with image-guided techniques.[5] Systematic review of EVD placement outcomes has revealed a successful placement rate of about 70%, necessitating multiple placement attempts in the remainder.[4,6,7] Each attempt increases complication risk, leading to incidences up to 40%.[2,8] Although image guidance has established benefits, its interventional use is limited in daily practice because of practical constraints.[9,10]

Conventional neuronavigation systems are prohibitively large and lack mobility, restricting their use to the operating room. Moreover, these systems necessitate unintuitive mental transformations of 2-dimensional information on remote displays into 3-dimensional (3D) action at the patient, dividing attention between both. Last, EVD placement frequently occurs in emergency situations where immediate access to OR resources is not guaranteed, with 74%-100% of placements occurring unnavigated at bedside.[7]

Augmented reality (AR) provides overlays of 3D information onto the real world and has the potential to augment the surgeon's view with relevant data. Smartphone-based EVD guidance has been proposed as a promising AR alternative to traditional navigation[11,12] but lacks accurate image-to-patient registration, resulting in suboptimal guidance. Umana et al[13] demonstrated acceptable EVD placement outcomes using an AR headset-based viewer for preoperative planning during simulation studies. Their work stopped short of an end-to-end workflow and relied on manual registration, suffering from the headset's well-known visualization drift.[14,15] When adapted with external or self-tracking technology, precise data and tool localization can be achieved.[16,17] This has allowed otherwise unsuitable AR hardware to achieve comparable image registration quality and improved tumor resection planning outcomes when compared with state-of-the-art neuronavigation systems.[18] Similarly, phantom studies have shown promising results toward AR-guided pedicle screw placement with trajectory errors of approximately 3 mm and 3°.[17] Regarding AR-guided EVD placement, Ansari et al[19] incorporated an external stereo-infrared tracker to provide tool localization in their phantom study. Their reported target error of 11 mm likely reflected manual instead of algorithmic image-to-patient registration. Regardless, adopting external tracking in these procedures is at odds with the goal of a readily available and portable system. We believe that a standalone AR navigation system is most suited for guidance of EVD placement, granting image guidance benefits while remaining mobile and intuitive in use.

To address shortcomings in EVD placement and current image guidance technologies, we first developed an AR headset-based

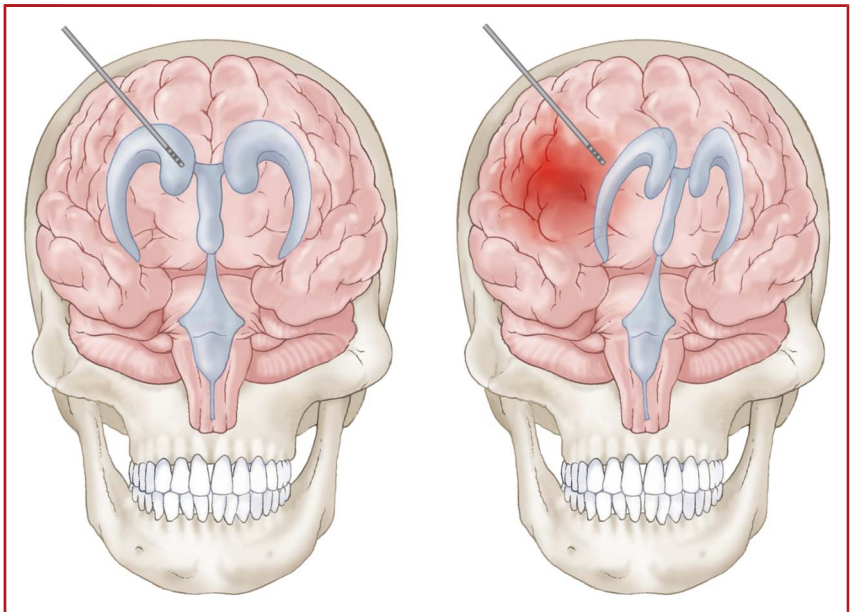

FIGURE 1. *Anatomical representation of the EVD placement procedure.* ***Left****, Normal anatomical situation is shown with a successful placement in the frontal horn of the right lateral ventricle, aimed toward the foramen of Monro as dictated by the guidelines.* ***Right****, Presence of an anatomy-altering pathology, such as an intraparenchymal hemorrhage, causes a significant distortion of the ventricles, which may result in a failed procedure when inserting the EVD at the same angle and depth. EVD, external ventricular drain.*

navigation system with high-accuracy inside-out infrared tracking and software features that specifically address EVD placement,[20,21] ensuring an end-to-end workflow with on-the-fly planning and real-time guidance. After successful phantom studies of AR-guided EVD placement,[22] we proceeded to test the system in a clinical trial.

METHODS

Study Design

A prospective clinical pilot study was designed to assess the feasibility, safety, and clinical performance of AR-guided EVD placement. This was quantified using a newly defined extended modified Kakarla scale (emKS),[2,23] described below, and through placement-related complications as secondary end points. Study protocol was approved by the Ethics Committee/Institutional Review Board of University Hospital Brussels (UZ Brussel; ref. 2018/447) and validated by the Belgian Federal Agency of Medicines and Health Products (ref. 80M0764). All researchers held a good clinical practice certificate and adhered to the Declaration of Helsinki. All participants and/or legal representatives signed informed consent (IC).

The manuscript describes the investigational use of a commercial AR headset, the Microsoft HoloLens 2, which is not labeled for use in a surgical setting, as well as an in-house created AR navigation system providing high-accuracy inside-out infrared tracking and software features addressing EVD placement. The former was approved for investigational use during the described study by the Ethics Committee of the University Hospital Brussels and the Belgian Federal Agency of Medicines and Health Products (cfr. supra). The latter is a noncommercial investigational system, created in-house for the described study. It was approved by the same instances and relied on previously validated accuracy results (mean tracking error: 0.78 mm ± 0.74 mm; mean image-to-patient registration error: 1.42 mm ± 0.42 mm, 0.95° ± 0.36°).

Patient Inclusion

Adult patients at UZ Brussel requiring EVD placement as sole primary intervention were eligible for study inclusion. IC was obtained before inclusion. For emergency cases where obtaining prior written IC was not feasible, consent was obtained retrospectively through an emergency-specific IC procedure approved by the Ethics Committee/Institutional Review Board. To define a nonconcurrent control group, nonenrolled patients who had undergone EVD placement were screened retrospectively on 3 criteria for correspondence with the investigated group: (1) bedside EVD placement using the freehand technique as sole primary intervention, (2) performed by a surgeon participating in the study, and (3) performed within the same time frame. From this screened cohort, an equal number of controls was randomly selected and assessed for usability (postoperative imaging <24 hours, no other confounding factors).

Augmented Reality

A high-accuracy, headset-based AR navigation system was developed to contain software features (data preprocessing, application design, image-to-patient registration, trajectory planning, drilling guidance), specifically addressing guidance for EVD placement.[20,21] These technical aspects, including visual illustrations, are outlined in detail in the supplemental digital content (see **Supplemental Digital Content 1** [http://links.lww.com/NEU/E662]; **Supplemental Digital Content 2** [http://links.lww.com/NEU/E663]; **Supplemental Digital Content 3** [http://links.lww.com/NEU/E664]; **Supplemental Digital Content 4** [http://links.lww.com/NEU/E665]; **Supplemental Digital Content 5** [http://links.lww.com/NEU/E666]; **Supplemental Digital Content 6** [http://links.lww.com/NEU/E667]; **Supplemental Digital Content 7** [http://links.lww.com/NEU/E668]).

Data Preprocessing and Application Design

A data preprocessing pipeline using the patient's preoperative imaging was implemented to allow efficient integration into the existing interventional workflow. This resulted in 3D models of the patient's anatomy along with predefined coordinates relevant for AR guidance, including the foramen of Monro as target point. The models were exported to the AR headset, a HoloLens 2 (Microsoft), into a surgical navigation application. The application integrated prior work on inside-out tracking of infrared-labeled medical instrumentation using the headset's infrared sensor,[18,20-22] resulting in accurate instrument tracking (mean tracking error: 0.78 mm ± 0.74 mm; unpublished Vicon validation testing), as well as image-to-patient registration (mean registration error: 1.42 mm ± 0.42 mm, 0.95° ± 0.36°).

Patient Registration, Trajectory Planning, and Drilling Guidance

Image-to-patient registration was achieved using an infrared-tracked stylus, accurately matching the 3D models to the patient's anatomy. During EVD trajectory planning, the system determined the path to the foramen of Monro with the shortest distance between the skin surface (region of interest of 25-mm radius around the stylus tip, usually starting from Kocher's point) and the ipsilateral frontal horn of the lateral ventricles. The surgeon was free to move the stylus around the expected entry point, taking into account underlying anatomy or pathology, until satisfied, after which the trajectory was confirmed. This trajectory line, as well as all visualized anatomical information, was displayed as a 3D object and could be inspected from all angles, providing a sense of depth. After attachment of a tracker to the surgical drill, the system indicated the respective translational and angular error of the drill bit's tip and drilling direction based on this trajectory. As soon as these errors were reduced below predefined thresholds of 2 mm and 2°, the trajectory's color turned green, indicating correct drill alignment. These thresholds translate into a worst-case target deviation of 3.7 mm at 5-cm depth, roughly corresponding to the diameter of the drill bit and EVD.

EVD Placement Protocol

After diagnostic CT, patients meeting inclusion criteria were prepped for AR-guided EVD placement (Figure 2). After preparation of the AR system and patient (installation and identification of Kocher's point), an infrared-labeled reference frame was attached to the patient's head by a clamping headband, allowing the AR application to track head position and orientation.

Next, the surgeon put on the AR headset and launched the EVD placement application. After registering the 3D models to the patient's anatomy, a patient-specific entry point was determined within a 1-cm radius of Kocher's point using the AR device. On completion of the standard presurgical protocol, a stab incision was made at the entry point through which the drill was inserted and aligned with the planned trajectory (Figure 3). The red trajectory color transitioning to green indicated correct alignment, after which drilling could proceed. During drilling, the trajectory color continued to indicate alignment quality.

After trepanation, the EVD was inserted, verifying its alignment with the still-visualized AR trajectory. As the craniostomy size (3.5 mm) was only marginally larger than the EVD diameter (3 mm), its position and direction effectively bounded the EVD's trajectory. The EVD was advanced to a depth of 5 cm into the ipsilateral frontal horn. After ventricular puncture, the EVD's inner stylet was removed and the EVD advanced atraumatically to a depth equal to the distance between the entry and target, as indicated by the AR system.

Outcome Measurement

On completion, ventricular puncture was often identified by consistent drainage of cerebrospinal fluid. Number of attempts was recorded, and a postoperative CT scan was performed within 24 hours to determine EVD positioning. Placement quality was graded using the emKS, with the EVD tip localization as decisive factor, by 3 investigators (FVG, FB, WG) separately. In cases of disagreement, arbitration was overseen by the supervising surgeon (JD) and consensus was reached. All procedure-related complications were documented. Hemorrhage volume was quantified using Elements software (Brainlab AG), isolating the hemorrhagic component between Hounsfield unit values 50-150 within the region of interest around the hemorrhage. System performance was assessed through video capture from the device camera and error logging, both with the intention of enabling post hoc analysis in case of system malfunction.

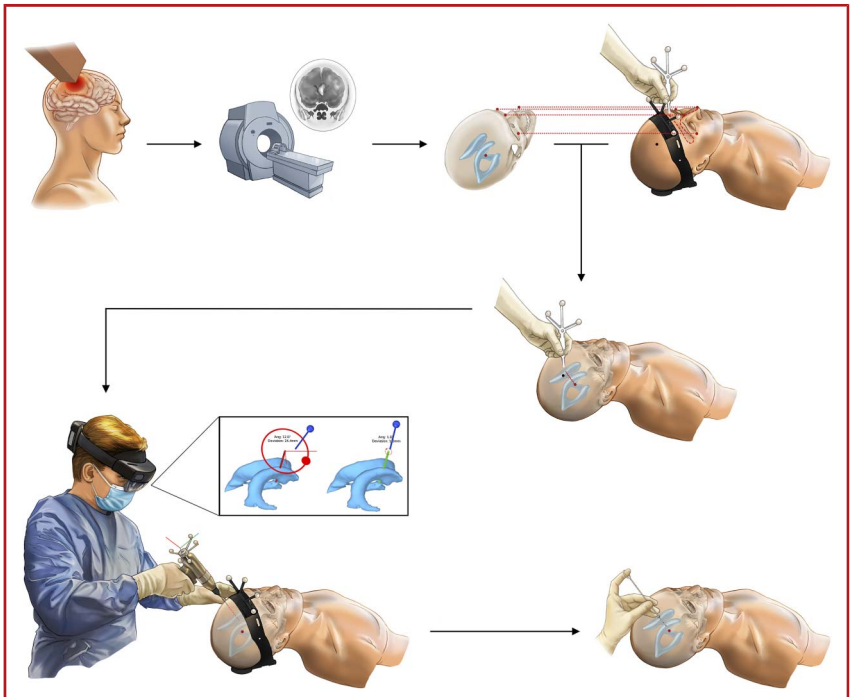

FIGURE 2. *AR-assisted EVD placement workflow.* ***First panel, top left****, Patient injury.* ***Second panel****, Diagnostic computed tomography scan to confirm indication for EVD placement.* ***Third panel****, Data preprocessing with identification of 4 anatomical landmarks along the patient's face (left and right lateral canthus, nasion, and tip of the nose, shown as red points relative to the patient's skin), and the target coordinate at the interventricular foramen of Monro (shown as a red point relative to the patient's ventricles).* ***Fourth panel, top right****, Image-to-patient registration: first indicating the 4 landmarks for initial alignment using the respective point pairs, followed by additional point collection along the bony landmarks of the face for refinement of the registration using an iterative closest point algorithm. At this stage, Kocher's point was identified as well (shown as a black point).* ***Fifth panel, middle****, AR visualization and EVD trajectory planning using the stylus to find the optimal entry point in the vicinity of Kocher's point, allowing the shortest distance to the ipsilateral frontal horn of the lateral ventricles (reference frame headband removed in drawing for better visualization).* ***Sixth panel, bottom left****, AR drilling guidance during trepanation, showing the surgeon the magnitude and direction of the respective translational and angular error of the drill bit's tip and drilling direction (through the 2 perpendicular red lines, and the red ring and dot, respectively) relative to the planned trajectory. Below the error thresholds of 2mm and 2°, the trajectory's color turned green, indicating correct drill alignment.* ***Seventh panel, bottom right****, Placement of the EVD along the planned trajectory (reference frame headband removed in drawing for better visualization). AR, augmented reality; EVD, external ventricular drain.*

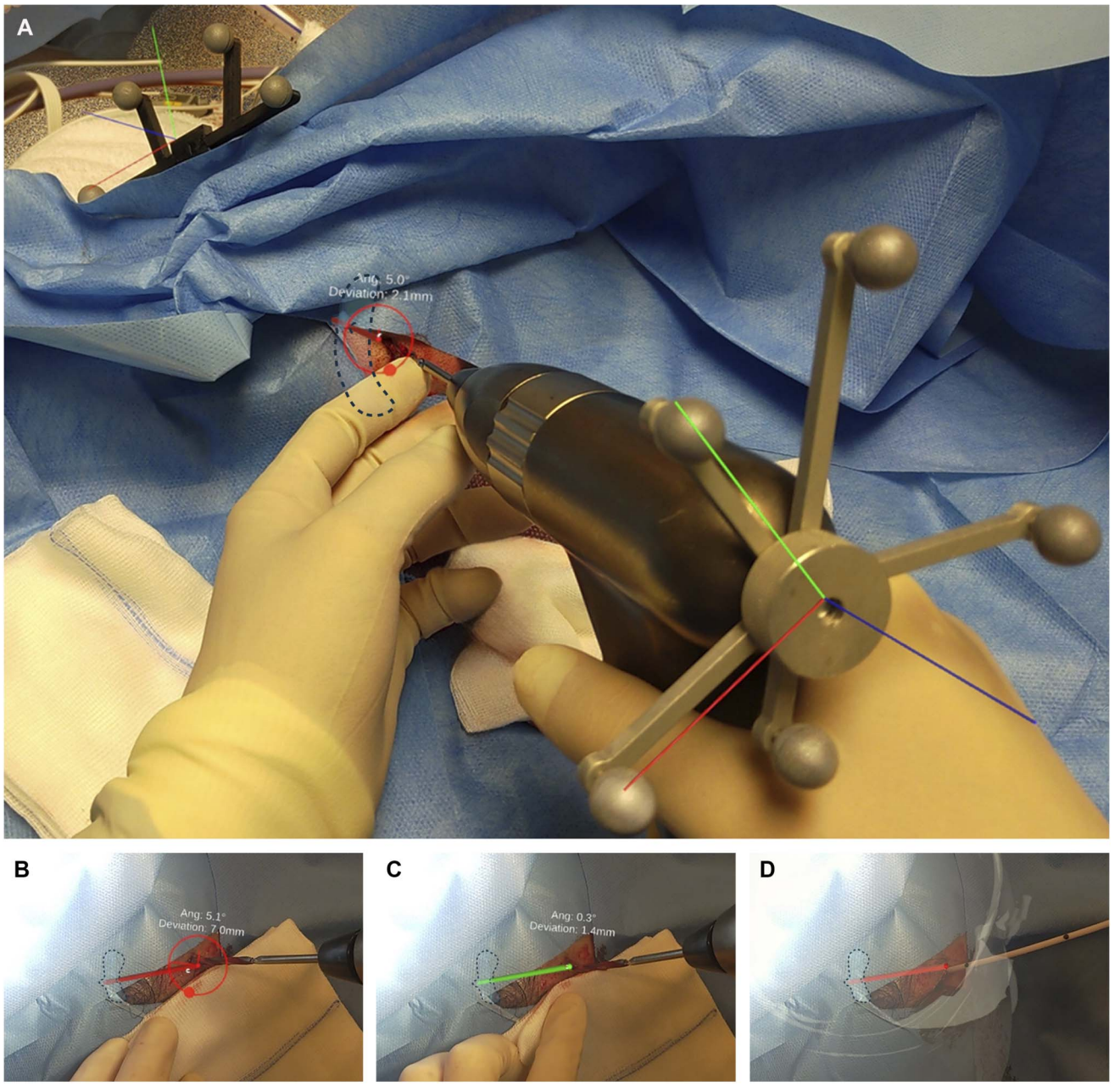

FIGURE 3. **A**, *AR-navigated drilling during EVD placement. Both the patient reference frame and drill tracker are recognized by the AR system (as shown by the x,y,z coordinate systems). AR guidance along the planned trajectory (in red) toward the ipsilateral frontal horn of the lateral ventricles (visualized in faded blue by the headset) is shown:* **B**, *at the moment of drill insertion,* **C**, *after correct alignment of the drill trajectory with the planned trajectory (turning green), and* **D**, *during EVD insertion. Indications of the translational and angular error are given in both numerical values and through visual representation of their magnitude and direction (ie, the 2 perpendicular red lines, and the red ring and dot, respectively). A dotted line along the ventricular contour was added in each photograph to enhance visibility of the faded ventricle visualization. AR, augmented reality; EVD, external ventricular drain.*

Statistical Analysis

Clinical EVD placement quality was reported as amount and percentage per emKS grade. These data were dichotomized into clinically relevant outcome parameters. Given the hypothesis of improved placement quality when using AR guidance on top of knowledge and experience regarding the freehand technique, as was the case for conventional neuronavigation,[3,5,9,10] along with the small sample size, the resulting dichotomous values were compared using one-sided Fisher exact

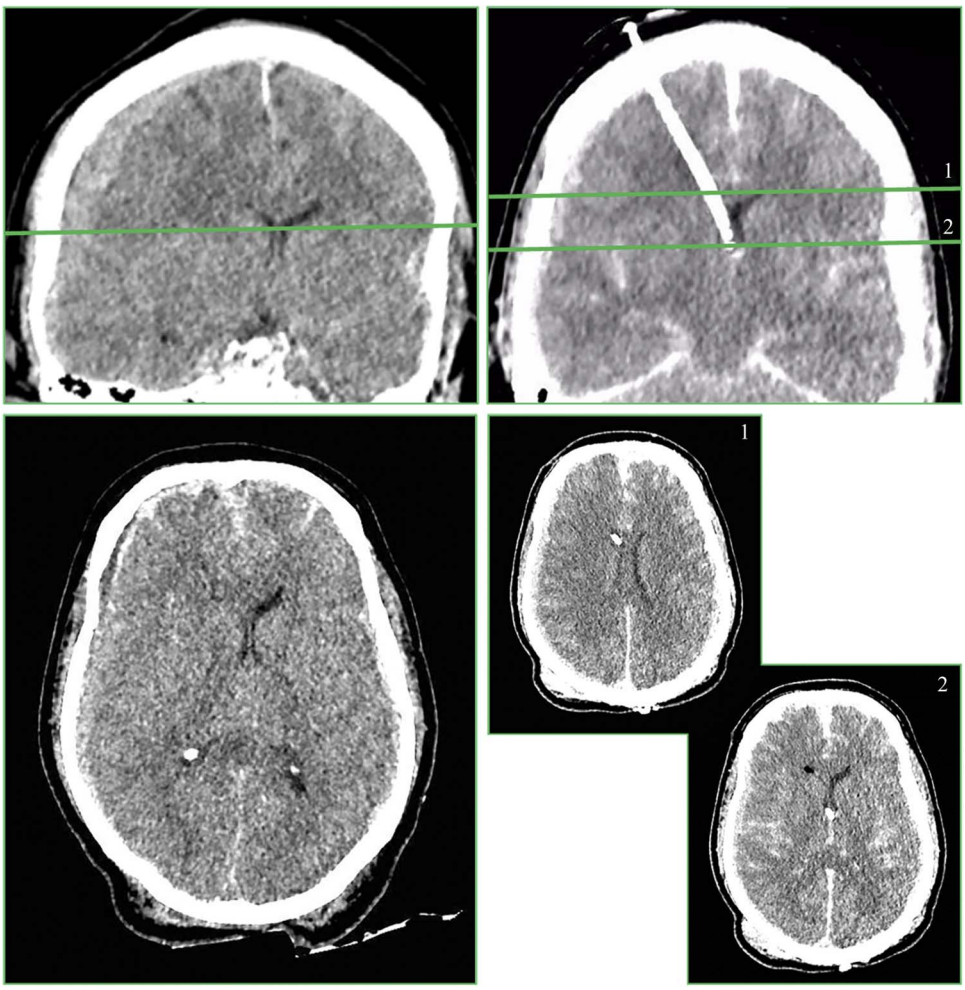

FIGURE 4. *Illustrative case of a patient with slit ventricles and midline shift after trauma:* **A**, *before, and* **B**, *after AR-navigated EVD placement in a single attempt. The corresponding level of the axial slices below is indicated with a green line on the coronal slices on top. AR, augmented reality; EVD, external ventricular drain.*

tests. Prism 10.2.3 (GraphPad Software) was used for statistical analysis. *P*-values <0.05 were considered statistically significant.

Data Availability

Deidentified participant data obtained through this study may be provided on request to qualified researchers with academic interest in AR guidance for EVD placement. Approval of the request (through a research proposal and statistical analysis plan) and execution of all applicable data-sharing agreements are prerequisites to the sharing of data with the requesting party. For request approval and following investigator support, contact Dr F. Van Gestel.

RESULTS

Patient Inclusion

In total, 22 EVD placements are reported: 11 using AR-assistance and 11 using the freehand technique. All were performed in the emergency room or intensive care unit by 4 different neurosurgical residents experienced in the freehand technique (see **Supplemental Digital Content 1** [http://links.lww.com/NEU/E662], **Supplemental Digital Content 6** [http://links.lww.com/NEU/E667], **Supplemental Digital Content 7** [http://links.lww.com/NEU/E668] for detailed surgeon characteristics and subjective technology experience).

AR-Assisted EVD Placement

In the AR-assistance group (n = 11, age_{mean} = 59 [24-85], male/female = 7/4), indications included the following: 4 spontaneous intraparenchymal hemorrhages (IPH) and secondary intraventricular hemorrhages (IVH), 3 aneurysm-associated hemorrhages (2 anterior communicating artery aneurysms, 1 mycotic posterior cerebral artery aneurysm), 2 neurotraumata (1 with diffuse subarachnoid

TABLE. Clinical EVD Placement Quality

Grade	EVD Quality	Tip Location	AR (n=11)	Freehand (n=11)
I	Optimal or Adequate	Ipsilateral frontal horn or 3rd ventricle	**9 (82 %)**	**5 (45 %)**
Ia	Optimal	no contact with ventricle wall	8 (73 %)	3 (27 %)
Ib	Adequate	contact with ventricle wall	1 (9 %)	2 (18 %)
II	Suboptimal		**2 (18 %)**	**5 (45 %)**
IIa	Functional	Contralateral lateral ventricle	2 (18 %)	2 (18 %)
IIb	Nonfunctional	Noneloquent tissue		3 (27 %)
III	Poor or Failed		**0 (0 %)**	**1 (9 %)**
IIIa	Poor	Eloquent tissue		
IIIb	Failed	Failed procedure		1 (9 %)

Clinically relevant outcomes	Corresponding emKS Grades			P-value
Functional	Grade Ia, Ib, IIa	11 (100 %)	7 (64 %)	**0.045**
Successful	Grade Ia, Ib	9 (82 %)	5 (45 %)	0.091
Optimal	Grade Ia	8 (73 %)	3 (27 %)	**0.043**
Failed	Grade IIIb	0	1 (9 %)	0.500
Revisions	Grade IIb, IIIa, IIIb	0	4 (36 %)	**0.045**
Complications		2 (18 %)	5 (45 %)	0.181

AR, augmented reality; EVD, external ventricular drain; emKS, extended modified Kakarla scale.
EVD placement outcomes as defined by the emKS (*adapted from Kakarla et al and Sarrafzadeh et al*[2,23]), demonstrating the placement quality using the AR guidance in comparison with the nonconcurrent controls using the freehand technique, along with the dichotomous analyses of the clinically relevant outcome parameters.

hemorrhage [SAH], 1 with multiple IPHs and diffuse axonal injuries), 1 IPH due to arteriovenous malformation, and 1 obstructive hydrocephalus after cerebellar stroke. Slit ventricles, as defined by near-complete obliteration of the ventricular space because of external compression or hemorrhage often combined with important midline shift (Figure 4A), were present in 2 cases. Their Evans index measured 0.21 and 0.24, respectively.[24]

Freehand Control Group

In the freehand control group (n = 11, age_{mean} = 53 [19-82], male/female = 6/5), indications included the following: 2 spontaneous IPH and secondary IVH, 4 aneurysm-associated hemorrhages (3 anterior communicating artery aneurysms, 1 posterior communicating artery aneurysm), 3 neurotraumata (1 with diffuse SAH/IPH, 1 with diffuse SAH/IVH, 1 with cerebral edema and IPH), and 2 infection-related indications (1 hydrocephalus after cerebellitis-induced cerebellar edema, 1 encephalitis-induced cerebral edema). There were no slit ventricle cases.

Clinical EVD Placement Quality

To attribute more weight to the consequences of different outcomes within mKS grades II and III, as was performed previously for grade I by Sarrafzadeh et al, we propose the emKS with similar subdivisions in both grades (Table).[2,23] These introduce a distinction regarding functionality in grade II placements, which determines the need for reintervention, and impact on prognosis in grade III placements.

As presented in the Table, optimal or adequate placement (grade I) was obtained in 9 cases (82%; 73% Ia, 9% Ib) in the AR group vs 5 (45%; 27% Ia, 18% Ib) in the freehand group. Suboptimal placement (grade II) in 2 (18%; 18% IIa) vs 5 cases (45%; 18% IIa, 27% IIb). There was 1 failed procedure (9%; 9% IIIb) in the freehand group. All AR-assisted cases were accomplished in a single attempt, including 2 grade Ia placements in the slit ventricle cases (Figure 4B). Number of attempts was not consistently documented in the control group.

Placement quality outcomes were dichotomized for functional (grade Ia-Ib-IIa), successful (grade Ia-Ib), optimal (grade Ia), and failed (grade IIIb) placements, as well as for number of revisions and complications (Table). This dichotomization revealed a significant placement quality improvement resulting from AR guidance, with functional placement in all cases vs 7 (64%) in the freehand group ($P = .045$); successful in 9 (82%) vs 5 (45%) ($P = .091$); optimal in 8 (73%) vs 3 (27%) ($P = .043$); and failed in 0 vs 1 (9%) ($P = .5$). No AR-guided placements required revision, whereas 4 freehand placements did ($P = .045$), resulting in a 36% reintervention rate. Procedure-related complications were encountered in 2 AR-guided cases (18%) vs 5 freehand cases (45%) ($P = .18$). All complications in the freehand group occurred after reintervention.

To determine source of error in the suboptimal AR-guided placements (grade IIa), subsequent procedure analyses were performed. This revealed erroneous hardware use as the origin in both instances: in the first, video analysis showed the patient reference being moved after registration; in the second, post hoc instrument inspection showed a bent drill tracker, resulting in incorrect tracking (see **Supplemental Digital Content 1** [http://links.lww.com/NEU/E662]—"Technical limitations" for more details).

Complications

The procedure-related complications in the AR-assistance group were both trajectory hemorrhages. The volume of 1 was small (0.18 cm^3), without mass effect or direct impact on outcome, whereas the other had a larger volume (9.16 cm^3), originating from an initial important IVH under anticoagulants. There was no procedure-related infection. In the freehand group, 5 procedure-related complications were recorded: 3 cases with hemorrhage after reintervention for nonfunctional (grade IIb) placement (1 acute subdural hemorrhage of 5.48 cm^3, 2 trajectory hemorrhages of 0.62 cm^3 and 0.28 cm^3) and 1 case with both trajectory hemorrhage (2.46 cm^3) and ventriculitis (not pertaining to the infection-related indications) after failed (grade IIIb) placement.

DISCUSSION

The goal of this study was to investigate the feasibility, safety, and clinical performance of AR assistance in EVD placement. The results confirm practicality and clinical performance of an AR navigation system for EVD placement. These findings were further underlined by the predominance of grade Ia placements, each accomplished within a single attempt. Compared with matched controls, significant improvement in clinical placement quality, attributed to the AR assistance, was observed. The results obtained with AR guidance showed a more than 2-fold increase in optimal placements, a reduction by half in suboptimal placements, and a complete absence of poor or failed placements. As all EVDs were functional on the first attempt, no reinterventions were required, as opposed to the freehand control group which had a 36% reintervention rate. These reinterventions, along with the implied multitude of attempts, constituted the primary cause of all procedure-related complications in the freehand group, once more emphasizing the hazard related to multiple stick-and-poke attempts and the importance of first-attempt success.

These findings display an improvement over literature-reported freehand placement results as well, with approximately 70%, 20%, and 5% for grades I, II, and III respectively, often requiring multiple attempts.[2,4,6,7] In comparison, the proposed method demonstrated a higher grade I placement rate, while exhibiting a similar grade II placement rate and an absence of grade III placements. It further outperforms previously reported first-attempt success rates of 78%[7] because all resulting EVDs functioned effectively on initial placement. Consequently, we saw a reduction of procedure-related complications to 18% as opposed to literature-reported incidences up to 40%,[2,8] which more closely correspond to the 45% complication rate of the freehand group.

Furthermore, post hoc analysis of the 2 AR-guided grade IIa placements revealed the deviation was caused by erroneous hardware use, rather than improper AR guidance or surgical technique. These cases are discussed more extensively in the Supplemental Digital Content (see **Supplemental Digital Content 1** [http://links.lww.com/NEU/E662]). Their occurrence highlights the need for integration of quality controls to detect suboptimal system use.

Although for some cases freehand placement might have been equally successful, the distinct improvement over the control group indicates that the freehand technique may not consistently yield straightforward results. The performance in slit ventricle cases further substantiates these presumptions because accomplishing successful ventricular puncture can be notably challenging, especially within a single attempt. In these cases the guidance benefit is expected to be the greatest.[25] In addition, the surgeons reported a positive tendency toward the system's acceptance (see **Supplemental Digital Content 1** [http://links.lww.com/NEU/E662], **Supplemental Digital Content 7** [http://links.lww.com/NEU/E668] for more details), acknowledging its utility, value, and ease of use with little to no discomforts, suggesting this technology not only tends to improve clinical outcome but also procedural ergonomics.

A self-contained AR navigation system is probably most suited for future work in EVD placement. As has been demonstrated in this work, this provides both high-accuracy and high-mobility surgical navigation without requiring an equipped operating room. Although the use of AR guidance introduces additional registration and planning protocols, previously timed at 1 minute 59 seconds,[18] these did not burden the workflow. Furthermore, our study introduced an interactive AR-based EVD trajectory planning workflow, providing surgeons with the shortest route through brain parenchyma. This feature allowed for on-the-fly adaptation to attain a patient-specific approach, in its current form mainly accounting for important anatomical deviations, such as

midline shift. Although Kocher's point serves as the statistically ideal entry, it does not account for anatomical variations or pathological distortions.[1] Additional value to this feature may be achieved through more elaborate planning, eg, involving underlying vessels and/or sulci.

Limitations

The study's main limitation is the small patient sample. However, we believe that the presented data, with the variety of afflictions, demonstrate safety, practical feasibility, and clinical advantages of the proposed method over the freehand technique. Owing to an uneven ventricle size distribution, which we would expect to be better balanced in larger samples, corresponding sizes could not be compared between both groups. Nevertheless, the presented situation favored the control group (lacking slit ventricle cases), yet AR guidance was still able to show improved performance. Addition of such cases might make the difference more significant.

Another limitation is the lack of time recordings for the AR group. However, within this study, it would result in unvalidated data because the retrospective controls did not provide a benchmark to compare with. Registration and planning workflows were previously timed at 1 minute 59 seconds,[18] and given the reported single-attempt success rate, the AR-guided procedure was usually concluded in <15 minutes.

The presented work serves as a base for future research, focusing on the upcoming validation phase through a large multicenter randomized controlled trial. In this study, we intend to implement more exhaustive metrics (including time) and comparisons, as well as standardized quality assurance protocols to address both design-related and technical limitations (see **Supplemental Digital Content 1** [http://links.lww.com/NEU/E662]).

CONCLUSION

The reported results demonstrate the first clinical use case of EVD placement using high-accuracy AR guidance contained in a standalone head-worn navigation system. Safe and reliable outcomes using a validated pipeline in a critical care setting were demonstrated, eliminating stick-and-poke attempts and resulting in improved quality, increased single attempt success rate, and reduced revision and complication rates. As such, AR-guided EVD placement provides a compact and intuitive alternative to conventional neuronavigation systems. Based on these results, a large multicenter randomized controlled trial will be initiated.

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Disclosures

The authors disclose a patent application (application number: WO2022144116A1) related to the augmented reality navigation technology described in this manuscript. It is important to note that this application was submitted after the completion of the clinical trial and did not influence the study design, execution, or data analysis. Furthermore, the patent application does not currently hold any commercial agreements or financial implications.

Registration

ClinicalTrials.gov protocol registration and results system (ref NCT06571539); Belgian Federal Agency of Medicines and Health Products (ref. 80M0764); University Hospital Brussels Ethics Committee/Institutional Review Board (ref. 2018/447).

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Supplemental Digital Content 1. Supplemental digital content.

Supplemental Digital Content 2. **eFigure 1A**; **Supplemental Digital Content 3**. **eFigure 1B**. Patient in the intensive care unit being prepped for the augmented reality (AR)–assisted external ventricular drain (EVD) placement procedure (the patient consented to the publication of their images). **(A)** A semirigid headband, equipped with an infrared-labeled reference frame, is clamped onto the patient's head to provide the augmented reality navigation system with a world-stable 3D coordinate system. **(B)** Using a handheld infrared-tracked stylus to identify the physical patient anatomy, the surgeon performs the image-to-patient registration process.

Supplemental Digital Content 4. **eFigure 2**. Representation of the planning phase before the augmented reality (AR)–assisted external ventricular drain (EVD) placement procedure. The black wireframe depicts the surface of the patient's skin, containing the lateral and third ventricles in blue. The position of the stylus' tip is indicated, as well as the point on the ventricles (p_v) and skin (p_s) closest to the tip. Centered around p_s, a search region (with radius r = 25mm) along the skin surface is defined, in which the point closest to p_v is determined as the suggested entry point (p_e). The resulting vector ($\vec{v_1}$), indicating the shortest path from skin to ventricles within the defined search region, is shown in green ($\vec{v_1} = p_v - p_e$). From p_e, the suggested EVD insertion vector ($\vec{v_2}$) toward the target point (p_m) at the interventricular foramen of Monro is shown in red ($\vec{v_2} = p_m - p_e$).

Supplemental Digital Content 5. eFigure 3. Illustration of the augmented reality (AR) drilling guidance for a planned external ventricular drain (EVD) placement procedure. **(A)** Ventricles are shown with the planned EVD insertion vector $\vec{v_2}$ (red line from the entry point (p_e) toward the target point at the interventricular foramen of Monro), as well as the drill bit's tip (blue sphere) and current drilling direction (blue line). The respective translational and angular error of the drill relative to the planned entry point and drilling direction are shown, both in numerical values and through visualization of the 2 perpendicular red lines centered at p_e, indicating the translational deviation of the drill tip from p_e, and the red ring and dot centered around p_e, respectively, indicating the magnitude and direction of the angular error between the current and desired drilling direction. In this example, the drill's tip is positioned in the lower right quadrant and its direction is aimed toward the top left quadrant. **(B)** Both the translational and angular error are reduced below the respective thresholds of 2mm and 2°, as indicated by the numerical values and the reduced size of the 2 perpendicular red lines and the red ring. As such, $\vec{v_2}$ is prompted to turn green, indicating correct alignment of the drill with the planned EVD insertion trajectory.

Supplemental Digital Content 6. **eTable 1**. Surgeon characteristics. EVD = external ventricular drain.

Supplemental Digital Content 7. **eTable 2**. Subjective technology experience. Values represent the median score (range) on a 5-point Likert scale for the Unified Theory of Acceptance and Use of Technology (UTAUT) model and system ease of use, and the total number of surgeons for the reported system discomforts.