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PRACTICAL ASPECTS OF NONCONVENTIONAL RADIOLOGICAL TECHNOLOGIES USED IN NEUROSURGERY CONSIDERING INTELLECTUAL PROPERTY PROTECTION

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ABSTRACT: The manuscript examines unconventional radiological practices, focusing on intraoperative ultrasound in neurosurgery and its clinical applicability for certain pathological entities. It argues that ultrasonographic methods offer practical benefits for patients and healthcare systems, including shorter operating times, improved tumour delineation, and real-time monitoring of procedures. Their relative availability, low costs, and ease of implementation make these procedures appealing alternatives for units with limited resources. Defining clear indications and optimising protocols remain key challenges, requiring standardised methodologies and specialised training programmes. We assess clinical efficacy and safety by implementing protocols, standards, and guidelines at national and international levels, protecting patients and maintaining system integrity. We suggest conducting multicentre studies, quality audits, and developing standardised protocols adaptable to diverse institutional capabilities. Ultimately, integrating intraoperative ultrasound into neurosurgery requires a multifaceted, evidence-based approach, ongoing education, and health policies that promote the responsible adoption of the technology for patient benefit. Economic, ethical, and legal considerations should also be incorporated into planning, including cost-effectiveness analyses, informed consent, and intellectual property protections. International collaboration is essential for uniform and sustainable implementation.

KEYWORDS: radiology, ultrasonography, management planning, healthcare evaluation.

1. INTRODUCTION

Technological advances in medical imaging have reshaped neurosurgical practices, providing tools that enable more precise intraoperative decision-making and reduced-risk interventions [1]. In the context of a healthcare system under pressure to be cost-effective and to ensure accessibility, “unconventional” radiological technologies, particularly intraoperative ultrasound (IUS), are gaining practical relevance. IUS provides real-time images, facilitating lesion localisation, resection margin assessment, and detection of immediate complications, without relying solely on complex infrastructures such as intraoperative MRI or neuronavigation [2]. In addition, the portability of the equipment and the comparatively low costs allow these technologies to be implemented in units with variable resources, providing a pragmatic solution to optimise operator flow and increase patient safety [2], [3].

The development and dissemination of medical technologies involve a complex balance between stimulating innovation through intellectual property protection mechanisms and the need for broad access to technology to improve patient care [4]. IP protection in imaging facilitates investments in research and development, ensuring compensation for innovative efforts and creating partnerships between clinical centres and industry [5]. At the same time, protective structures can constitute barriers to local adaptation of technologies, to interoperability, and to the exchange of know-how within health networks, especially in resource-constrained settings. IP rights become relevant when image processing algorithms or analysis software modules are integrated into the surgical workflow, an integration that raises questions about data ownership, algorithmic licensing, and clinical liability in the event of algorithmic error [6].

Therefore, a responsible implementation strategy must include measures to protect inventions and, simultaneously, mechanisms for equitable technology transfer: flexible licensing agreements, public–private partnerships, institutional innovation management policies, and legislative frameworks that enable clinical validation, quality audits, and equitable access to benefits [7]. Integrating IP considerations into clinical trial design and implementation protocols ensures the protection of inventors and the methodological transparency necessary for reproducibility and patient safety [8], [9].

This paper aims to provide a practical and integrated analysis of unconventional radiological technologies in neurosurgery. It focuses on evaluating the clinical indicators and practical utility of intraoperative ultrasound for specific pathological entities and identifying procedural advantages and limitations from the patient and healthcare system perspectives.

2. THEORETICAL FOUNDATION AND CRITICAL REVIEW OF THE LITERATURE

2.1 Evolution of radiological techniques in neurosurgery: from conventional to unconventional

Neurosurgical imaging has experienced a significant shift in recent decades, evolving from the predominant use of preoperative radiography, computed tomography (CT), and magnetic resonance imaging (MRI) to the adoption of intraoperative tools that complement or partially replace these modalities at various stages of surgery [10], as seen in Figures 1 and 2. The development of MRI/CT-based neuronavigation and the subsequent integration of functional imaging have improved planning accuracy [11], [12]. However, logistical constraints and the high cost of intraoperative MRI (iMRI) have led to the use of unconventional technologies as practical solutions for real-time visualisation, especially in units with varying resources [13]. Once marginalised, IUS has seen technological advancements that have broadened its clinical applications from mass detection to evaluating lesion resection margins and vascularisation [14], [15]. Simultaneously, hybrid technologies, such as combining IUS with neuronavigation, have been proposed to address the limitations of each method [16].

Figure 1. Intraoperative ultrasound integrated with a neuronavigation system.

Figure 2. Integration of preoperative CT images with ultrasound analysis, using eSaote intraoperative ultrasound to identify anatomical landmarks.

2.2 Physical and technological principles of intraoperative ultrasound and other unconventional modalities

Ultrasound is based on the emission of ultrasound waves and the interpretation of the echoes reflected at the interface between tissues with different impedances. In the intraoperative context, essential parameters include probe frequency, examination modes (B-mode for morphology, Doppler for vascular flow, elastography for tissue consistency), and software calibration to correct for artefacts caused by air or tissue manipulation [17], [18], [19]. Advantages of IUS include real-time imaging, portability, and relatively low cost [20]. Limitations include lower resolution than MRI in some contexts, post-resection artefacts, and a learning curve for use and interpretation [18], [21]. Ultrasound elastography provides tissue stiffness data, which are useful for characterising tumour margins [22], [23]. Integrating image processing and fusion software algorithms is critical to reducing correlation errors between pre- and intraoperative images [24], [25].

2.3 Synthesis of clinical trials and meta-analyses: efficacy, limitations and gaps in evidence

The published literature includes case series, nonrandomized cohort studies, and several comparative studies evaluating the impact of IUS on tumour resection rate, operative time, and postoperative outcomes [20], [26]. Recent meta-analyses indicate that the use of IUS is associated with increased complete resection rates in certain types of brain tumours and reduced reoperations, but methodological heterogeneity across studies limits generalizable conclusions [27], [28]. Comparative studies between IUS and iMRI show distinct advantages of each method: iMRI offers superior anatomical resolution and assessment without surgical interference, but at a much higher cost and complexity [29]. IUS offers flexibility and real-time imaging but may underestimate tumour margins in diffuse lesions [21], [28]. Significant shortcomings include the lack of robust multicentre randomised trials, the lack of standardisation of IUS protocols, and the lack of long-term evaluation of functional outcomes and cost-effectiveness [30], [28].

2.4 Organisational models and therapeutic uses in different health systems

Adopting unconventional technologies varies considerably depending on institutional resources, national policies, and training capacity [31], [32]. Tertiary centres in developed countries tend to integrate IUS into a multimodal set (IUS + neuronavigation), supported by protocols and interdisciplinary teams; in resource-limited countries, IUS is often adopted as the primary intraoperative technology due to its low cost and portability. However, its implementation is frequently fragmented, reliant on individual initiatives, and lacks standardised training [31]. Successful models include centralised training programmes, tele-support systems for interpretation, and public–private partnerships facilitating access to equipment and mentors [32]. Economic evaluations indicate that implementing IUS can be cost-effective, particularly if it reduces re-interventions and hospitalisation duration. Nonetheless, outcomes are sensitive to caseload, equipment availability, and maintenance costs [20].

Table 1. Synthetic comparison of the technical, clinical and economic characteristics of the main intraoperative technologies.

Criteria	Intraoperative Ultrasound	Intraoperative MRI	Neuronavigation
Main Advantages	Real-time imaging, portability, low cost, no radiation, visualization of vascular flow (Doppler).	Excellent spatial resolution, superior tissue contrast, gold standard for glial tumour resection.	Precise anatomical orientation, real-time approach guidance, minimally invasive.
Limitations	Image quality is operator-dependent, bone artifacts, steep learning curve.	Enormous costs, prolonged surgical time, requires non-magnetic tools, brain shift between scans.	Brain shift phenomenon, data becomes inaccurate after dural opening, no real-time imaging.
Approximate Cost	Low to Moderate (€30,000 - €100,000)	Very High (> €1,500,000)	Moderate to High (€150,000 - €400,000)
Required Infrastructure	Minimal; compact mobile unit, dedicated transducers.	Complex; shielded hybrid suite (Faraday cage), patient transport system, magnetic controlled zone.	Moderate; computerized workstation, IR/electromagnetic camera system, microscope integration.
Clinical Impact	Excellent for real-time resection monitoring and partial compensation for brain shift.	Maximum impact in neuro-oncology for identifying microscopically non-visible tumour remnants.	Essential for trajectory planning and localizing deep-seated or small lesions.

3. CLINICAL INDICATIONS AND PRACTICAL APPLICABILITY

3.1 General indications for the use of intraoperative ultrasound in neurosurgery

Intraoperative ultrasound (IUS) is a valuable tool in any neurosurgical procedure. In neurosurgery, real-time visualisation guides treatment decisions [33]. Typical indications include locating and characterising intracranial lesions, guiding cortical approaches and access routes, evaluating tumour resection margins, detecting haemorrhages or acute collections, assessing vascular perfusion with Doppler modes, and monitoring for immediate complications [34]. IUS is especially useful when preoperative image-based neuronavigation may be inaccurate due to intraoperative topographic changes, such as brain shift [35].

3.2 Applicability in brain tumours

In gliomas, IUS is effective for delineating the tumour mass, identifying areas of density differentiation, and monitoring resection [36]. In high-grade gliomas, IUS can increase the rate of gross resection [37]. However, its sensitivity for detecting small residual tumour volumes is lower than that of postoperative MRI, particularly in extensive infiltrative lesions [38].

For brain metastases, especially well-demarcated ones, IUS has high value for localisation and confirmation of complete resection, and integration with Doppler can assess vascularity [33]. The cost-benefit is favourable in settings with high metastatic case volume and limited access to iMRI [20].

Figure 3. Intraoperative ultrasound image of a secondary brain lesion, evaluating the lesion's consistency and margins, as well as the neighbouring blood vessels, using the Doppler module.

In meningiomas, IUS provides useful morphological information for identifying the tumour margin and the relationship with superficial vascular structures; in the case of meningiomas in superficial areas, ultrasonographic resolution is often sufficient for planning resection, although in the case of bone invasion or in the vicinity of venous sinuses, MRI remains a relevant complementary imaging modality [32].

3.3 Usefulness in the treatment of vascular lesions, hematomas and vascular malformations

Doppler-mode IUS helps identify intraoperative vascular flow, confirming flow after clipping or thrombectomy, and detecting superficial vascular malformations [34]. In acute and subacute intracerebral hematomas, IUS allows for precise localisation of the collection and guidance of evacuation, reducing operative time and the potential for additional trauma [26]. For deep vascular malformations, the role of IUS is more limited due to limited access and resolution. However, when combined with neuronavigation, it provides complementary information on vascular topography [39].

4. PROTOCOL AND SURGICAL TECHNIQUE

4.1 Equipment configuration and technical considerations

The configuration of the intraoperative ultrasound (IUS) system must follow the criteria of robustness, ergonomics and clinical-organisational compatibility. The choice of ultrasound platform starts with practical considerations: ease of mobility in the operating room, an intuitive interface, extensive post-processing capabilities [40], and DICOM export for integration into the patient file and institutional records [41]. The probes are assigned distinct roles depending on the depth and nature of the lesion: high-frequency probes (≈10–15 MHz) provide superior axial resolution for superficial lesions, while lower-frequency probes (≈5–8 MHz) allow greater penetration for deep lesions [42], [43]. Linear and convex probes are used for different clinical applications [44].

Software capabilities are another critical element: B-mode for morphology, colour Doppler for vascular assessment, and, where available, elastography for tissue consistency estimation should be accessible and calibratable. Speckle reduction filters, preoperative image fusion options (IUS–MRI/CT), and volumetric measurement tools enhance the clinical value of IUS and help reduce correlation errors between preoperative and intraoperative imaging [45], [46]. Institutional policies should document minimum technical specifications to standardise equipment acquisition and maintenance [47].

Sterility and handling issues must not be overlooked. The operating protocol should incorporate protective foils dedicated to sterile probe adapters and clear decontamination procedures. In recent decades, significant technological advances have enabled ultrasound probes to be sterilised, as shown in Figure 4. Cable management [48], monitor positioning [49], and hands-free capabilities [50] enhance ergonomics and minimise the risk of flow contamination or disruption during operation. Additionally, verifying the electromagnetic compatibility of the IUS system with other devices in the operating room, such as neuronavigation and electrocautery, is crucial to avoid technical interference that could compromise imaging acquisitions.

Figure 4. The BK intraoperative ultrasound probe, after complete sterilisation, can be used directly in the operative field.

4.2 Intraoperative scanning technique and essential steps

The IUS method is carried out in well-defined stages, integrated into the operative flow as seen in Table 1.

Table 2. The necessary steps for using the intraoperative ultrasound machine.

No.	Steps	Description
1	Initial pre-resection scan	after cortical exposure and ensuring optimal contact between the probe and the parenchyma, B-mode imaging is performed to define the topography of the lesion, following the echogenic limits, location, and relationship with adjacent vascular structures. If necessary, the Doppler mode is activated to assess vascularisation.
2	Verification scans during resection	Repeated rapid acquisitions allow reassessment of the resection margins, detection of ultrasonographically visible residues, and early identification of haemorrhages or other complications.
3	Final post-resection scan	a systematic assessment of the surgical cavity to identify detectable debris, collection of representative images/stills and their storage in DICOM format for quality audit and clinical documentation.

To minimise artefacts, the operator must properly manage the probe-tissue interface: avoid air between the probe and the parenchyma, maintain constant pressure, and reduce sudden movements. In cases where the surgical cavity contains air, frequency adjustments and post-processing presets can improve image quality [51].

4.3 Team Role and Competency Requirements

Effective use of IUS intrinsically depends on operator competence and clarity of team roles. It is recommended to designate an IUS operator, a trained surgeon, or a technician responsible for imaging setup, acquisition, and documentation. Distinct tasks, probe manipulation, parameter settings, capture, and DICOM export, should be clearly communicated in the preoperative briefing. Training programs should include structured practical modules, competency assessment, and clinical mentoring, given the operator-dependent effect reported in the literature.

Institutional certification of personnel involved, along with periodic updates, workshops, and case feedback sessions, may reduce interpretive variability and increase the consistency of results. Tele-mentoring and remote support programs may be helpful in centres with limited experience.

4.4 Operator time management and workflow integration

To minimise the impact on the intervention's duration, plan the integration of IUS in a process-oriented way. The additional time associated with an acquisition is generally reduced to a few minutes; however, it includes the initial setup, component sterilisation, and image interpretation. Concrete optimisation measures: preoperative preparation of the equipment, definition of a dedicated operator, use of presets and checklists, and adoption of a “fast scan” protocol for punctual reassessments [52], [53].

Periodic audits of intervention duration and comparisons between cases with and without IUS enable the identification of stages with potential for optimisation. The accumulated experience tends to reduce the additional time required for iMR procedures in centres with high case volume; however, for IUS, the learning curve might be slower, and reducing surgical times may require more interventions than initially considered [54].

4.5 Documentation, storage and quality monitoring

Rigorous documentation of IUS acquisitions, probe parameters, presets used, key frames, and reference videos is indispensable for quality audits, research, and forensic management. Standardising the data structure, mandatory metadata: patient identifier, procedure type, acquisition time, operator, and centralised storage in DICOM format, allows interoperability and facilitates multicenter analyses [55].

The institutional registry should include a minimum set of operational indicators to support performance audits and cost-effectiveness studies [56].

5. SAFETY, EFFICACY AND QUALITY MONITORING

5.1 Measuring clinical outcomes: efficacy and safety indicators

Evaluating the impact of unconventional radiological technologies in neurosurgery should be based on clear sets of quantifiable, reproducible and clinically relevant indicators. Efficacy indicators include complete resection rate, postoperative tumour volume reduction, and the frequency of reoperations for residual disease or complications. Safety indicators include incidence of surgical complications, functional scores at standardised follow-up periods of 30, 90 days, 6 months, mortality, and serious adverse events directly related to imaging. Additionally, operational quality indicators are relevant: the average additional time required to integrate intraoperative imaging, the percentage of interventions in which the IUS modified the surgical plan, and the DICOM storage rate for audit [57], [58].

5.2 Audit systems, registry and multicenter studies

Implementing an institutional registry for IUS cases, with standardised image and metadata collection, facilitates quality auditing and retrospective or prospective research. We propose standardised multicenter protocols for defining inclusion criteria, probe settings, scanning steps, and definitions of complete resection and functional assessment indicators; such studies would reduce current heterogeneity and enable robust cost-effectiveness analyses [59].

6. ETHICAL, LEGAL AND INTELLECTUAL PROPERTY PROTECTION

6.1 Informed Consent and Communication of Technological Risks/Benefits

Informed consent should explain the nature of the technology, the purpose of its intraoperative use, differences from the current standard, therapeutic alternatives, and specific risks, including the risk of operator-dependent interpretation errors. Communication should include protecting personal data and the possible use of images for teaching or research purposes, with the option to obtain separate consent [60].

6.2 Intellectual Property Protection: Patenting, Copyright, Licensing, and Technology Transfer

Patents protect technical innovations, including hardware and software, but can constrain access without an equitable licensing policy [63]. Copyright covers source code and documentation; licensing models facilitate adoption in resource-constrained settings [64], [65]. Academic institutions should engage technology transfer offices early and negotiate terms that allow for scientific dissemination and responsible clinical use [66].

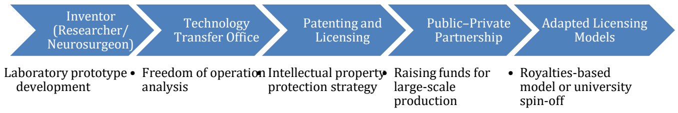

Figure 5. Diagram of the protection and technology transfer process for imaging devices.

7. DISCUSSION

7.1 Critical interpretation of results and clinical implications

The literature review and synthesis of practical experience indicate that unconventional radiological technologies, especially intraoperative ultrasound (IUS), offer real potential to improve intraoperative decision-making by providing real-time images, operational flexibility, and relatively low initial and operational costs compared to high-end alternatives such as iMRI [28]. The benefits seem clearer in specific clinical contexts: well-demarcated lesions such as metastases, superficial meningioma, and hematoma evacuation, where IUS contributes to rapid localisation, confirmation of resection, and reduced need for reintervention.

However, the conclusions must be tempered by the methodological limitations of the available evidence. Most studies are observational, with predominantly nonrandomized designs, which limits the ability to directly attribute variations in clinical outcomes to IUS use. Heterogeneity in technique, probe types, settings, operator proficiency, and resection assessment criteria reduces comparability between series and emphasises the need for standardised protocols and objective outcome measures. In infiltrative gliomas, the limits of ultrasonographic resolution and the difficulty of differentiating infiltrative tumour tissue from edema or reactive tissue remain significant obstacles, which is why multimodal integration, such as IUS + neuronavigation + preoperative imaging, seems the most promising way to maximise clinical utility [21], [35]. Regarding implementation, IUS emerges as a complementary tool rather than a universal substitute for iMRI, offering a pragmatic balance between cost, access and clinical benefit [29].

7.2 Ethical, legal and intellectual property protection issues

Introducing and using intraoperative imaging technologies involves multiple ethical and legal considerations. Informed consent should reflect not only the procedural risks and benefits, but also the implications for image storage, research or educational use, and potential limitations of proprietary software components or integrative algorithms. Transparency in communicating that specific software modules may be proprietary, and that interpretation depends on operator competence, is essential for valid consent [67].

From a legal perspective, decision-making responsibility remains with the physician. Still, questions arise regarding contractual liability and the guarantees offered by software/equipment providers, issues that need to be clarified through contracts and institutional policies at the time of acquisition [6]. Also, software medical device (SaMD) regulations, CE/FDA markings, and post-market surveillance requirements apply and must be followed to ensure compliance and patient safety [68].

8. CONCLUSIONS

Intraoperative ultrasound and other unconventional radiological technologies offer practical, cost-effective options to enhance neurosurgical practice, particularly in resource-limited settings where high-end infrastructure like iMRI is inaccessible [54], [33], [72] however, translating these benefits into measurable, sustainable clinical outcomes demands a comprehensive, multifaceted approach: generating rigorous evidence through multicenter randomized trials and standardized protocols [73] underdosing technical procedures to minimize operator variability [74]; providing structured professional training [74]; establishing equitable intellectual property policies that balance innovation with accessibility [74]; implementing robust regulatory frameworks [68]. This responsible deployment strategy prioritises patient safety, optimises health system efficiency, and fosters ongoing innovation [75]. Furthermore, future investigations should incorporate larger, more heterogeneous patient populations spanning multiple institutions to corroborate existing findings and enhance their applicability in neurosurgical contexts [76], [77].

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