

Review of first clinical experiences with a 1.5 Tesla ceiling-mounted moveable intraoperative MRI system in Europe

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ABSTRACT

High-field intraoperative MRI (iMRI) systems provide excellent imaging quality and are used for resection control and update of image guidance systems in a number of centers. A ceiling-mounted intraoperative MRI system has several advantages compared to a conventional iMRI system. In this article, we report on first clinical experience with using such a state-of-the-art, the 1.5T iMRI system, in Europe. A total of 50 consecutive patients with intracranial tumors and vascular lesions were operated in the iMRI unit. We analyzed the patients' data, surgery preparation times, intraoperative scans, surgical time, and radicality of tumor removal. Patients' mean age was 46 years (range 8 to 77 years) and the median surgical procedure time was 5 hours (range 1 to 11 hours). The lesions included 6 low-grade gliomas, 8 grade III astrocytomas, 10 glioblastomas, 7 metastases, 7 pituitary adenomas, 2 cavernomas, 2 lymphomas, 1 cortical dysplasia, 3 aneurysms, 1 arterio-venous malformation and 1 extracranial-intracranial bypass, 1 clival chordoma, and 1 Chiari malformation. In the surgical treatment of tumor lesions, intraoperative imaging depicted tumor remnant in 29.7% of the cases, which led to a change in the intraoperative strategy. The mobile 1.5T iMRI system proved to be safe and allowed an optimal workflow in the iMRI unit. Due to the fact that the MRI scanner is moved into the operating room only for imaging, the working environment is comparable to a regular operating room.

KEY WORDS: Intraoperative MRI; mobile MRI; brain tumors; neuronavigation; moveable intraoperative MRI system; iMRI

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INTRODUCTION

In the 1990s, pioneers such as Fahlbusch and Black developed first intraoperative MRI systems (iMRI) [1-7]. A variety of them are currently available, with field strengths ranging from 0.15T to 3T. The iMRI systems with a field strength of 1.5T, or more, offer an excellent imaging quality and are used for resection control and update of the image guidance systems (IGS) to compensate for the brain shift [8]. Although expensive, such system may not only improve the extent of tumor resection but can also increase the safety of neurosurgical procedures by integrating the data of diffusion tensor imaging (DTI)-based fiber tracking and functional MR

imaging (fMRI) [9-12]. The latest generation of these systems includes a ceiling-mounted moveable MRI scanner which is placed outside of the operating room (OR) and is moved on ceiling-mounted rails into the OR only for the acquisition of intraoperative scans [13-15]. This concept was first described in 1999 by Sutherland, who reported the preliminary results for a single-room system implementing a ceiling-mounted moveable 1.5T MRI scanner [16, 17]. After introducing the first such system in Europe, in 2010, we describe the first clinical experiences with using this state of the art, 1.5T iMRI unit.

MATERIALS AND METHODS

Patients and pathologies

In this retrospective study, we included 50 patients (31 men and 19 women) with a mean age of 46 years (range 8 to 77 years). All the patients were operated on in the iMRI unit. Patients with brain tumors, vascular lesions and one patient

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with a Chiari malformation were included in the series of our first group of patients.

Operating room setup and special technical equipment

The iMRI system (Visius Surgical Theatre, IMRIS Germany) was integrated into existing hardware. Several technical modifications had to be done, including the ceiling rails, laminar airflow, electrical system and the radio frequency (RF) shielding of the room.

The completed iMRI unit consisted of an OR (51 m² excluding the MRI scanner bay) with an MRI bay that was separated from the OR by two sliding steel doors, a technical room, a control room and the waiting area for the surgical team in front of the OR (Figure 1). The OR and the MRI scanner bay were in the same laminar airflow system and were both within the sterile area. The OR table could be rotated 180° and tilted in all directions. The time required to bring the MRI scanner to the position needed for scanning (7 m from the MRI scanner bay to OR table) was 1 minute and 35 seconds.

The installed MRI scanner, a MAGNETOM Espree (Siemens, Erlangen Germany) provided a 70cm MRI scanner bore. In addition to the standard sequences, it was equipped with the following special sequences for intraoperative image acquisition: 3D CISS (Constructive Interference in Steady State) and 3D DESS (Double Echo Steady State), Chemical Shift Imaging, Single Voxel Spectroscopy, Spectroscopy Evaluation syngo, fMRI Trigger Converter, Inline BOLD Imaging, BOLD 3D Evaluation syngo, 3D PACE syngo, Susceptibility Weighted Imaging (SWI), Inline Perfusion, Diffusion Tensor Imaging, Inline Diffusion.

A state-of-the-art, voxel-based image guidance system (CBYON™ - Med-Surgical Services Inc., Sunnyvale California, USA) was also integrated into the iMRI unit. This guidance system, using three dimensional (3D) volumetric image rendering, allowed modulation of the opacity of tissue layers. For evaluation of DTI and fMRI data, the IGS was equipped with the NeuroQLab software (Mevis Fraunhofer, Bremen, Germany) as shown in Figure 2.

Additional MR-compatible equipment included a ventilation machine Aestiva/5 MRI (GE Healthcare Madison, WI, USA) and Covidien MRidium IV Infusion Pumps (Siemens, Erlangen, Germany), using wireless remote control. For a complete integration of all multimedia data, the iMRI unit was equipped with a system (Black Diamond Video, Point Richmond, CA) capable of distributing, recording, editing and storing video data in full HD format.

Workflow in the iMRI unit

Anesthesiological preparation and patient positioning

All the patients received an arterial line placement in the radial artery, for intra-arterial blood pressure monitoring, a central venous catheter, and had intravenous access obtained. All the patients were intubated with an MRI-compatible tube and received an MRI-compatible urinary catheter placement. After anesthesiological preparation was completed, a safety checklist was reviewed by the anesthesiologist and the surgical nurse. If intraoperative monitoring (IOM) was required, special platinum needles (MedCaT GmbH, Munich, Germany), that can be left in place during the MRI scan, were used.

A head clamp was put on the patient by the neurosurgeon and then, the patient's head was positioned. All ferromagnetic objects were moved outside the 5-gauss zone, and a final checklist was reviewed (Figure 3 A). The MRI scanner was then moved out of the MRI bay into the OR.

The image acquisition and neuronavigation

For the preoperative scans, no draping of the patient was necessary. The intraoperative scans were acquired using the procedure described above; however, the patient had to be covered with a sterile plastic bag for an intraoperative scanning, (Figure 3 A) to keep the surgical field sterile. The upper part of the head coil was then placed on top of the covered patient and fixed in position, using only a Velcro band. Three employees measured the exact height and position of the OR table with the patient on it so that the patient's head could be placed in the isocenter of the MRI scanner bore



FIGURE 1. View from the MRI scanner bay into the OR showing the back side of the MRI scanner (A). The completed iMRI unit consists of an OR (51m² excluding the MRI scanner bay) The control room contains the MRI consol and the satellite station as well as the IGS planning station and a touch screen control for the multimedia unit (B). Two separate monitors were installed for the surgical team in the waiting area allowing the team to view MRI images as they are acquired. In the background next to the OR door the anesthesiological workstation (C).

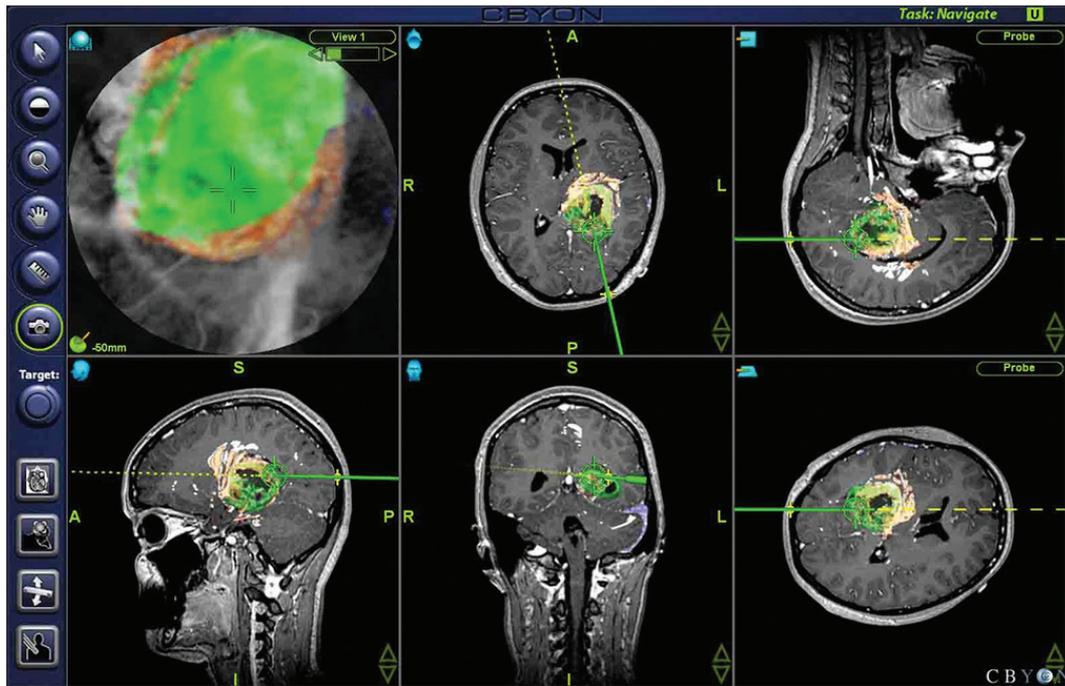


FIGURE 2. Intraoperative screenshot of the CBYON™ IGS showing in the upper left image the 3D “virtual endoscopic view” with the tumor segmented in green and the displaced DTI based fibertracks in orange. Due to the reduced opacity, the tissue layers surrounding the tumor become translucent clearly showing the tumor. The other images show the position of the registered stimulator, acting as a pointer during intraoperative stimulation of the fiber tracts.



FIGURE 3. The patient is shown covered (A) with a sterile plastic bag to preserve sterility of the surgical site. The head coil is placed on top of the patient’s head and is held in place with a Velcro band. In the background, it can be seen that all ferromagnetic objects are positioned outside the 5-gauss zone. In the middle, the mobile nurses’ desk is shown next to tables with the surgical instruments covered with sterile drapes. On the wall one of the two 65” Monitors are seen. In the background, the surgical nurse, the running nurse, and the anesthesiologist are shown while performing the final check before moving the MRI scanner out of the bay. The MRI is in the “safety check position” 20 cm in front of the OR table. Three people are checking the correct height and position of the OR table with the patient on it (B) so that after insertion into the MRI the patient’s head is in the isocenter of the MRI scanner bore (C).

(Figure 3 B, C). The MRI scanner automatically stopped in a “safety check position,” which was 20 cm before reaching the OR table so all final adjustments to the table position could be made before the MRI scanner bore was moved over the patient. Additionally, the MRI was equipped with a special touch sensor mounted around the MRI scanner bore that immediately stopped the instrument on contact.

RESULTS

Pathologies and the extent of resection

Patients’ data and treated pathologies are listed in Tables 1 and 2. The median number of scans per surgery was 2 scans

with a median duration of 47min per MRI scan (range 6 to 115 min). Intraoperatively, a remnant tumor was seen in the iMRI scans in 29.7% (n=11) of all tumor patients (n=37), which lead to a change in surgical strategy and continuation of the resection. Based on the iMRI scans, a gross total resection (GTR) was achieved in 35 patients (94.6%). The intraoperative monitoring (IOM) of motor- and sensory-evoked potentials was performed in 14 (37.8%) out of 37 tumor patients. The IOM also included cranial nerve monitoring, during which all the needles could be left in place without causing burns in the patient, or artifacts in the MRI scans. In two patients suffering from brain tumors located in eloquent areas, the resection had to be stopped due to deterioration of MEPs (Motor Evoked

TABLE 1. Types of pathologies operated in the iMRI unit

Pathology	Number of patients
Glioblastoma	10
Astrocytoma	8
Low grade glioma	6
Metastasis	7
Pituitary adenoma	7
Cavernoma	2
Lymphoma	2
Cortical dysplasia	1
ACI aneurysm	3
AVM	1
EC/IC Bypass	1
Clival chordoma	1
Chiari malformation	1

AVM- arteriovenous malformation, ACI- internal carotid artery, EC/IC- extracranial/intracranial

TABLE 2. The number of patients treated and the summary of results with median times of the different steps required for surgery in the iMRI unit

Total number of patients		50
Patients with tumors (gross total resection achieved)	37	35 (94.6%)
Gender (male/female)	31	19
Mean age/range	77	8-46
Anesthesiological preparation (median time)	35 min	(range 17 – 58 min)
Patient positioning and safety checks (median time)	63 min	(range 18 – 106 min)
Surgical procedures (median time)	5 hours	(range 1 – 11 hours)
Duration of intraoperative scanning (median time)	47 min	(range 6 – 115 min)

Potentials) in the IOM. In both patients, only a subtotal tumor removal could be achieved. None of them suffered from new permanent neurological deficits postoperatively. The IGS was used in 20 (40%) out of 50 patients.

The intraoperatively acquired MRI scans were evaluated by a senior neuroradiologist who was in charge of the MRI, together with the neurosurgeon, who determined whether or not to proceed with the resection. The new intraoperatively acquired images were fused with the preoperative images, thereby updating the IGS. In 6 patients, an intraoperative DTI (Diffusion Tract Imaging) sequence was acquired to visualize the fiber tracks for precise intraoperative navigation guided stimulation (Figure 2). Evaluation of the preoperative and intraoperative DTI-based fiber tracking data was performed using the NeuroQLab software (Mevis Fraunhofer, Bremen, Germany) and imported into the IGS for intraoperative use.

There were no complications during any of the MRI-guided surgeries. Neither the imaging, nor the surgery had to be interrupted due to problems with anesthesia, or technical problems. There were no accidents or inconveniences involving ferromagnetic objects, and no early postoperative infections occurred in any of the patients treated in the iMRI unit.

DISCUSSION

The positive impact of achieving a GTR on the survival of patients with malignant brain tumors has already been reported in the literature [18-20]. Among all available intraoperative imaging modalities, the iMRI still offers the best image quality. A lot has changed since the initial introduction of the iMRI to the OR in the mid-nineties, by pioneers in this field such as Fahlbusch and Black [1-4]. The computer technology that has evolved today allows not only fast MRI-based fiber tracking and functional imaging during surgery but also intraoperative evaluation of diffusion and perfusion [21]. Nimsky et al. have demonstrated the influence of intraoperative fiber tracking on the surgical outcome in patients with tumor [2, 10, 12]. Also, integration of multimedia data in the OR is available today, improving the workflow of iMRI systems compared to the first systems that were more or less "home-made". The ergonomic issue for the neurosurgeon performing the surgery was also not considered very important in the past because the focus was set mainly on acquiring the intraoperative MR images. This was especially true for the double donut iMRI system [22].

Besides the initial costs of installing an iMRI system, high maintenance costs and overall higher costs for each surgery due to prolonged surgical time, have to be considered. Therefore, for the economic reasons, it should be possible to use the iMRI not only for intraoperative imaging but also for diagnostics whenever the scanner in the OR is not in use [14].

Fixed vs. mobile MRI scanner

The first option was a system with a fixed MRI scanner, requiring a specialized iMRI OR with a permanent high noise level in the room, produced by the helium pump. Here, the patient had to be rotated into the MRI scanner [23]. An alternative solution was a fixed system with the MRI scanner outside the OR. Here, however, the patient had to be transferred into another room with all the ventilation tubes and vascular line placements and was then transported to the MRI scanner on the hospital stretcher bed [24]. The other option was a system with a mobile MRI scanner where the scanner was outside the OR then moved to the patient location [13, 14, 16, 17]. Unfortunately, the experience with high-field mobile intraoperative MR scanners in Europe was limited since no system with a mobile MRI scanner had been installed so far. Advantages and encouraging results of dual room systems with a mobile MRI scanner from other parts of the world have previously been published [13, 14]. For safety reasons, we did not prefer to transfer the patient from the OR table to the MRI scanner, which was required when using a Miyabi or similar system. Considering the arguments above, we decided

to install the Visius Surgical Theatre (IMRIS, Winnipeg) iMRI system incorporating a mobile 1.5T MRI scanner.

Workflow and safety issues

It can be argued that the only difference between the mobile system with the high-field iMRI and other high-field iMRI systems is the fact that the MRI scanner hangs from the ceiling. However, this seemingly minor variation does make a significant difference in the workflow and patients' safety since neither the OR table nor the patient has to be moved for intraoperative imaging. Even though no safety issues have been reported regarding the movement of the patient from the OR table into the MRI scanner, this potentially does represent a risk. We noticed that with the ceiling-mounted MRI scanner, the patient does not have to be moved with all the intravenous line placements, catheters, and ventilation tubes during the procedure, and this reduces the potential risk for the patient.

Besides the obvious advantages of the iMRI system, the additional time required for such procedures is frequently discussed, because of the anesthesiological risks and a higher risk of infections. It can be argued that the patient is potentially exposed to a higher anesthesiological risk, due to the prolonged surgical times in an iMRI. However, little data were published on this topic, and no data are available on the assessment of the higher anesthesiological risks due to longer surgery times in an iMRI. In our first series of patients, we did not observe an increased rate of infection or anesthesiological complications. These findings were concordant with the results of other centers using a ceiling mounted iMRI [13-15].

The median time for patient preparation was 35 minutes (range 17 to 58 minutes), which was concordant with the preparation times for a routine surgery at our clinic. Analyses also showed that the median duration during the first 25 cases was 45 minutes and after that 35 minutes. Overall, these findings were in agreement with increased preparation and surgery times in other centers using an iMRI [13-17].

Patient positioning is relevant for any surgical procedure but is extremely important for surgeries in the iMRI unit since the surgery times are considerably longer. An MR-compatible head clamp was used (DORO®, pro med instruments GmbH, Freiburg, Germany). The maximal inclination in the prone position was not always possible, because the head clamp mount would have reached outside the 70 cm diameter of the MRI scanner bore. However, it did not influence the surgical outcome in any of the cases. The median time for patient positioning was 65 minutes (range 43 to 89 minutes) for the first 25 cases, and 57 minutes (18 to 106 minutes) for cases after that.

There were no available data on the best ways to perform the IOM in an iMRI without removing the needles. As a result,

a setup was developed using special MR-compatible platinum needles (MedCaT GmbH, Munich, Germany). Nonetheless, the median additional time required in the iMRI unit was 62% longer than for a regular surgery at our clinic. Also, temporary pressure marks on the skin with formation of blisters were observed in only 3 patients (6%) after a median surgical time of 5 hours (range 1 to 11 hours). However, special dermatological treatment or surgical treatment of the skin lesions was not necessary in any of these cases.

Intraoperative imaging and neuronavigation

The median number of scans taken per surgery was 2 (range 1 to 4). The median duration of an MRI scan was 47 minutes (range 6 to 115 minutes), which was comparable to results reported by other authors using a similar system [14]. After the scan, the images were transferred automatically to the IGS (CBYON™ - Med-Surgical Services Inc., Sunnyvale California, USA) where they were fused with the preoperative images. This way, new patient registration was not required intraoperatively. Another advantage of the intraoperative image fusion using the CBYON™ IGS was the fact that by fading the fused intraoperative images in and out, tumor remnants can quickly be identified and marked as targets in the IGS for fast and accurate localization.

Resection control, IOM and first clinical results

Lesions generally considered suitable for surgery in the iMRI OR include brain tumors such as low-grade gliomas, astrocytomas, pituitary adenomas and craniopharyngiomas [22, 24-28]. Authors have reported on other pathologies that can be operated in an iMRI OR. However, no definite benefits for the patients have been found so far. The main advantage of an iMRI was an intraoperative resection control and the update of the IGS. Therefore, brain tumors are the primary indication for surgery in an iMRI. Out of 50 patients operated in our iMRI unit, 37 patients (74%) suffered from brain tumors, and in 29.7% of these cases the intra-operative strategy was changed, and resection was continued leading to a GTR in 94.6% of all patients with a tumor. Other authors reported similar data with a modified surgical strategy, ranging from 28.8 to 54% [13, 25, 29, 30]. Also, our rate of achieving a GTR was concordant with findings in other centers using a high-field MRI where GTRs ranged from 90 to 99% [13, 25, 30]. It can be argued that surgeries in an iMRI unit should always result in a 100% GTR. In our series, however, in two cases the surgery had to be stopped due to the deterioration of evoked potentials recorded during the IOM. In both patients, only temporary postoperative neurological deficits were observed, which resolved by the time of discharge from the hospital. This emphasizes the great importance of combining imaging and

monitoring modalities intraoperatively, to preserve the neurological function.

An argument against the high-priced iMRI is that in patients with high-grade gliomas a GTR can be achieved in 65% using 5-ALA (5-Amino-Levulinic-Acid), compared to 36% using only white light [31, 32]. These numbers are based only on the extent of resection, not reporting the functional outcome, as we previously reported [33]. Furthermore, low-grade gliomas rather than high-grade gliomas represent the best indication for iMRI surgeries. In this first group of patients operated in our iMRI unit, no comparison between 5-ALA-based resections and iMRI-based resections was performed; however, such a study has been performed by the Erlangen group [34].

Similarly, as described for the 5-ALA, the neurosurgeon has to find a balance between achieving a GTR of the visualized tumor and preservation of neurological function [33]. Especially when performing tumor resections in eloquent areas of the brain, not everything visualized on the intraoperative MRI scan can be removed without intraoperative monitoring, brain mapping and subcortical stimulation.

Drawbacks

Besides the considerable cost of purchasing a high-field iMRI system, we found the prolonged surgical times as the biggest drawback. Our results showed that the duration of surgeries in the iMRI unit was prolonged by 20% to 50%, compared to the average time for routine brain tumor surgeries at our clinic, due to the time necessary for adequate patient positioning, patient preparation and scanning times. This represented a considerable increase in time and therefore in the cost of these procedures. Since the mean overall cost for one minute in the OR in Germany is estimated to be 15 Euros, it was not possible to cover the cost of these surgeries with the money currently paid by the insurance companies in Europe [35]. Therefore, prospective studies are necessary to prove the apparent benefits of such systems for the patients and through that achieve adequate compensation from health insurance companies.

CONCLUSION

The mobile 1.5T iMRI system proved to be safe and allowed an optimal workflow in the iMRI unit. Since the MRI scanner can be moved into the OR only for imaging, the working environment is comparable to a regular OR. However, long-term follow-up and more experience with this state-of-the-art system are necessary to scientifically evaluate all its benefits for neurosurgical procedures. In almost half of the cases, the tumor resection was extended based on the iMRI scans, showing the value of this imaging tool. The combination of

iMRI and IOM showed that IOM adds a great value to an iMRI system.

DECLARATION OF INTERESTS

The authors declare no conflict of interest.

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