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CLINICAL ARTICLE - FUNCTIONAL

Surgical implantation of STN-DBS leads using intraoperative MRI guidance: technique, accuracy, and clinical benefit at 1-year follow-up

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Abstract
Background Improvement of surgical accuracy during DBS-lead implantation has been described recently, leading to "frameless" or "MRI-verified" techniques. However, combining a high-quality definition of the STN using intraoperative 1.5 MRI with the possibility to reduce errors due to co-registration and to monitor lead progression during surgical insertion while checking the absence of surgical complication is an appealing method. We report here surgical methodology, safety, application accuracy, and clinical benefit of STN-lead implantation under MRI guidance.
Methods Two patients with a severe PD state were treated by bilateral STN–DBS. Leads were implanted under general anesthesia using intraoperative MRI guidance (ClearPoint system). Lead implantation accuracy was measured on T1 axial images at the level of the target. Clinical improvement was measured on the pre- and post-UPDRS 3 scale at 1-year follow-up.
Results Surgery was safe and uneventful in both cases. Radial error was 0.36 (right) and 0.86 mm (left) in case 1, and 0.41 (right) and 0.14 mm (left) in case 2. No edema or hemorrhage were noticed.
Conclusions Intraoperative MRI guidance allows DBS lead implantation with high accuracy and with great clinical efficacy. A larger cohort of patients is needed to confirm these initial results.

Keywords DBS · Subthalamic nucleus · MRI · Parkinson disease

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Introduction

Subthalamic nucleus (STN) deep brain stimulation (DBS) is an effective and well-established treatment for severe Parkinson's disease (PD) [2]. Recently, this procedure has been demonstrated to be valuable even at the early stage of the disease [18]. STN-DBS is also being investigated to treat psychiatric disorders such as obsessive–compulsive disorder (OCD) [3, 14]. Clinical feedback during surgery is not always obvious, especially in those later indications, and as a result,

precise targeting and intraoperative checking of the final position of the lead are crucial.

Classical STN targeting is based on two complementary procedures. Indirect targeting uses stereotactic and probabilistic atlases [5, 17] and anatomical landmarks (anterior commissure, posterior commissure, mid-commissural point), and is most often confirmed by micro-electrode recording (MER) and intraoperative stimulation. Direct targeting, has gained interest with the improvement of MRI images definition and is already advocated by many authors [23].

It consists of the visualization of the target on high-quality MRI scans, then performing surgical implantation based on it. Classical methods vary among teams but they usually use preoperative stereotactic MRI and in some groups, CT-scans, co-registered in the stereotactic space into a single 3D imaging for surgical planning. This implies the use of a rigid frame fixed on the patient's head. The systematic use of MER and intraoperative micro-stimulation depends on experience of each team and is performed to check the optimal position of the lead within the motor part of the STN, in awake or anesthetized patients.

STN is actually a small structure located at the diencephalic–mesencephalic junction, with a complex oblique three-dimensional lens shape. The anterior part of the STN matches with an iron-rich area, appearing in T2-hyposignal and located anteriorly and laterally to the red nucleus and posterolaterally to the substantia nigra (SN) [5]. In clinical routine, STN is easily individualized at the diencephalon–mesencephalic junction on MR scans at 1.5 or 3 Tesla. However, delineating the STN on MRI sequences does not prevent from unsatisfactory surgical implantations for several reasons.

First, target choice and trajectory planning are often based on image fusion performed automatically or manually based on pre-op T2 and T1 MRI scan, and, when needed, CT scan, which can lead to errors. The use of a frame-based or frameless technique of implantation also carries some imprecision with a range of error between 1.5 and 3 mm in average. Furthermore, delineation of the STN is not always optimal, especially on its inferolateral part close to the substantia nigra pars reticulata (SNr) and may require sedation of the patient in order to obtain high-quality images. On the other hand, indirect targeting may also lead to some errors because of the same reasons mentioned above, but also due to inter-individual variability of the position of the STN, notably on its laterality relative to the midline and due to the lack of precision of non-deformable atlas.

Secondly, optimal trajectory does not imply optimal final direction of the lead that can be deviated from its original route. To minimize this error, intraoperative imaging is used in many centers and requires, to improve accuracy, an operation room equipped with a tele-X-ray apparatus to minimize magnification errors and to allow co-registration between 2D X-ray images and 3D MRI.

Several attempts to improve the surgical technique have been described recently, leading to "frameless" techniques [11] or to "MRI-verified" techniques [22–24, 26].

However, combining high-quality definition of the STN using intraoperative MRI obtained under general anesthesia with the possibility to reduce errors due to co-registration of several set of images in the same stereotactic space, and to monitor lead progression during surgical insertion while checking the absence of surgical complication is an appealing method that has recently been developed by the group from the University of California San Francisco (UCSF) [22, 24].

Here we report our preliminary experience of STN leads positioning using intraoperative 1.5-Tesla MRI guidance in two patients suffering from severe PD and followed for at least 1 year.

Methods

MRI suite

Surgery was conducted in the neuroradiology department at the Grenoble University Hospital, with a regular MRI diagnostic suite (Philips 1.5 Tesla Achieva®).

This MRI machine is routinely used for patients requiring general anesthesia and a specific surgical decontamination was performed prior to the surgery in accordance with the procedures usually used in neurosurgical operative rooms (OR).

Patients

Two patients with advanced PD were selected to undergo DBS electrode placement with intraoperative MRI guidance. They were chosen either on their impossibility to undergo surgery under local anesthesia because of the severity of the disease and difficulty of communication, or simply as a personal choice for general anesthesia. Patients agreed to be operated on using this new technique and gave their informed consent to the surgeon. Preoperative and postoperative motor assessment was carried out according to the CAPIT protocol [15].

Preoperatively, patients were assessed on the same day off medication after an overnight withdrawal of dopaminergic medication and after a levodopa challenge using 120 % of their morning dopaminergic medication dose. "Postoperatively, patients were evaluated 1 year after surgery on the same morning in four conditions: off-medication/on-stimulation, off-medication/off-stimulation, on-medication/off-stimulation, on-medication/on-stimulation. For the on-medication condition, the same dose of levodopa used in the preoperative levodopa challenge was used after surgery. Each

condition was kept for at least 45-60 min before the assessment.

Preoperative UPDRS IV scores were used to analyze duration and severity of dyskinesia and motor fluctuations. Patients underwent a neuropsychological evaluation both before and 1 year after surgery.

Surgical steps: See Figs. 1, 2, 3, and 4

The surgical methodology has already been precisely described by the pioneer group that developed this technique [8]. We strictly followed their technique using the same "ClearPoint" system, which consists of an aiming device (SmartFrame) and dedicated software for interventional MRI (iMRI) that allows a bilateral lead implantation. The only difference was that we performed a larger bi-coronal skin incision and deliberately used a sharp stylet to cross the dura instead of a wide opening of the dura when inserting the stylet and the lead (3389®, Medtronic, Minneapolis, MN, USA).

The patients were shaved and put under general anesthesia and monitored in the MRI suite for the entire surgery. They were installed in the bore and fixed in a magnetic-field-compatible head-holder with flexible head coiled and fixed on each side (see Fig. 1). Patients were given cefazolin 2 g iv at the beginning of the surgery followed by cefazolin 1 g iv, 4 h afterwards. Then, during surgery, Rifadin was locally irrigated at the level of the skin incision and burr hole.

A first T1 MRI acquisition was performed, with a stuck grid on each pre coronal scalp area. This sequence allowed to determine a preliminary trajectory and the entry point that was marked at the surface of the skin bilaterally (see Fig. 2). Then we used a direct and indirect visualization of the STN as we always do in "regular cases" with T2 MRI sequences providing a precise visualization of the dorsolateral STN but also with usual indirect landmarks (AC-PC and mid-commissural point).

After the large bifrontal incision, a burr hole was drilled on each side and then the two platforms (SmartFrames) were anchored to the skull. The aiming devices were mounted on the platforms and orientated roughly to the middle of the cranium on each side (Fig. 3a and b). A new fast T1 MRI sequence was acquired to align the center of the platform with the trajectory (Fig. 3c). When needed, the trajectory was modified with a remote system fixed on the ring of the platform (Fig. 3d) that allowed to correct pitch and roll. The next step consisted of inserting a sharp stylet without opening the dura and a new T1 MRI sequence was acquired to check the trajectory of the stylet (Fig. 4a).

The final step involved the insertion of the chronic lead (3389®, Medtronic, Minneapolis, MN, USA) using a peel-away sheath and the acquisition of new T1 MRI sequences (axial) to check the position of the active contact with respect to the target defined above (Fig. 4b-c) and the absence of any complications. The sheath was then removed and the electrode was secured to the cranium with a cap (Medtronic-cap®, Medtronic, Minneapolis, MN, USA). The same procedure was applied for the contralateral side; the two mounting devices were removed and then the skin was sutured after Rifadin irrigation.

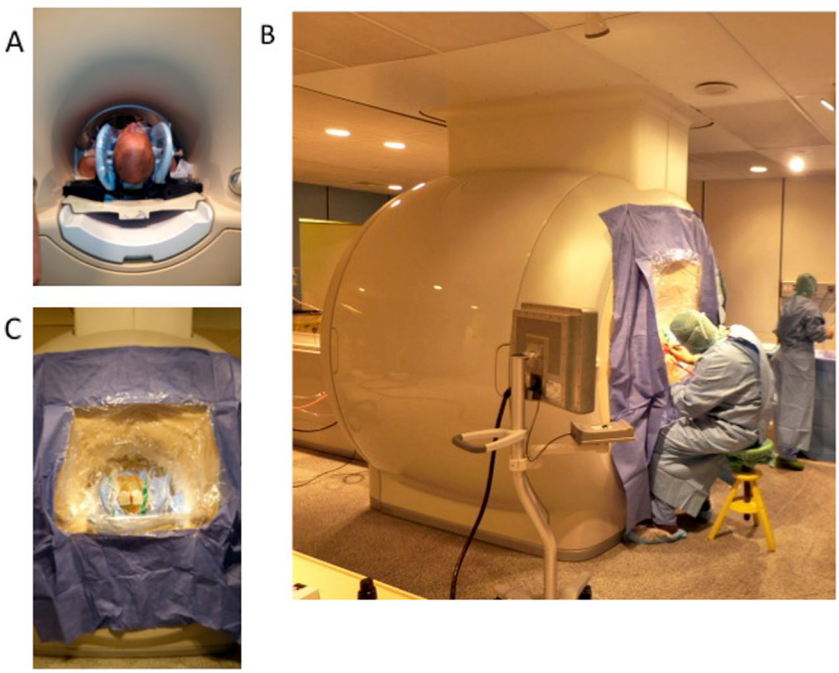

Fig. 1 Overview of the MRI suite during surgery. **a** The head is fixed on a magnetic high-field-compatible head-holder fixed to the MRI table with flexible head coiled and fixed on each side. **b** General view of the surgery inside the MRI suite. **c** Overview of the draping stuck on the head of the patient and on the border of the MRI machine. The draping allows the back and forward movement of the patient into the bore

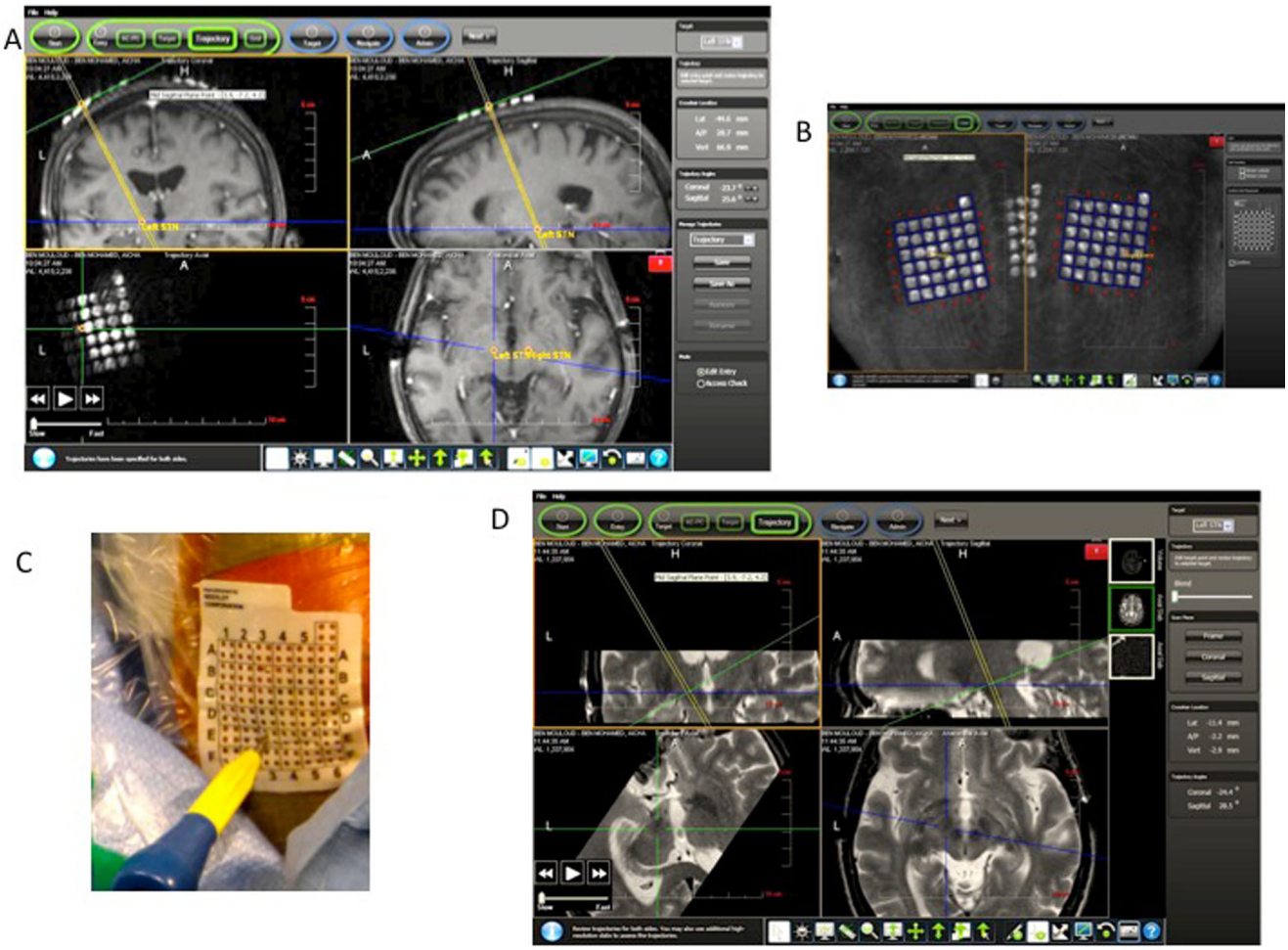

Fig. 2 First image acquisition and definition of the entry point on the scalp. **a** A T1 injected axial sequence is obtained and a probabilistic trajectory is defined. **b**, **c** The entry point is marked on the grid stuck on the scalp. **d** A T2 axial sequence is obtained to define the target based on consensual definition of the STN (direct and indirect targeting)

The implanted pulse generator (IPG) battery (Activa SC, Medtronic, Minneapolis, MN, USA) was implanted 2 days later.

Results

The surgery was uneventful, well tolerated in both patients, and no post-operative complication was noted aside from a transient postoperative euphoria in patient 2 that occurred in the first days after surgery (beginning after implantation and lasting for 10 days). There was no need to intensive care unit stay, the patients turned back in conventional neurosurgical unit immediately after recovery room. Total duration of hospitalization was shortened in both cases by approximately 5 days, as compared to the average duration of hospitalization of about 10 days in the neurosurgery unit. Surgery lasted 8 h for patient 1 and 6 h for patient 2. The IPG battery was inserted 2 days after to allow a second post-op MRI 2 days after lead implantation. Final intraoperative MRI showed the lead inserted in the STN with a radial error of 0.36 and 0.86 mm for R and L STN in case 1, and 0.41 and 0.14 mm for R and L STN in case 2. Neither edema nor hemorrhage were noted around the lead in this final intraoperative MRI, while some edema was noted in both cases in the MRI scans obtained 2 days after surgery.

After immediate post-operative period, there were no longer dyskinesias. Motor fluctuations disappeared in patient 2 and was consistently reduced in patient 1. Postoperative motor UPDRS scores, LEDD and MATTIS score are reported in Tables 1, 2, 3, and 4.

At a 1-year follow-up, UPDRS III was improved by 36 % and 65 % during On Stim condition compared to baseline condition in patients 1 and 2, respectively. In patient 1, treatment was slightly increased by 30 % because of persisting freezing of gait during On Stim. For patient 2, postoperative LEDD was reduced by 88 %, compared to the pre-op state. Tremor was not controlled by medication during baseline whereas it was well

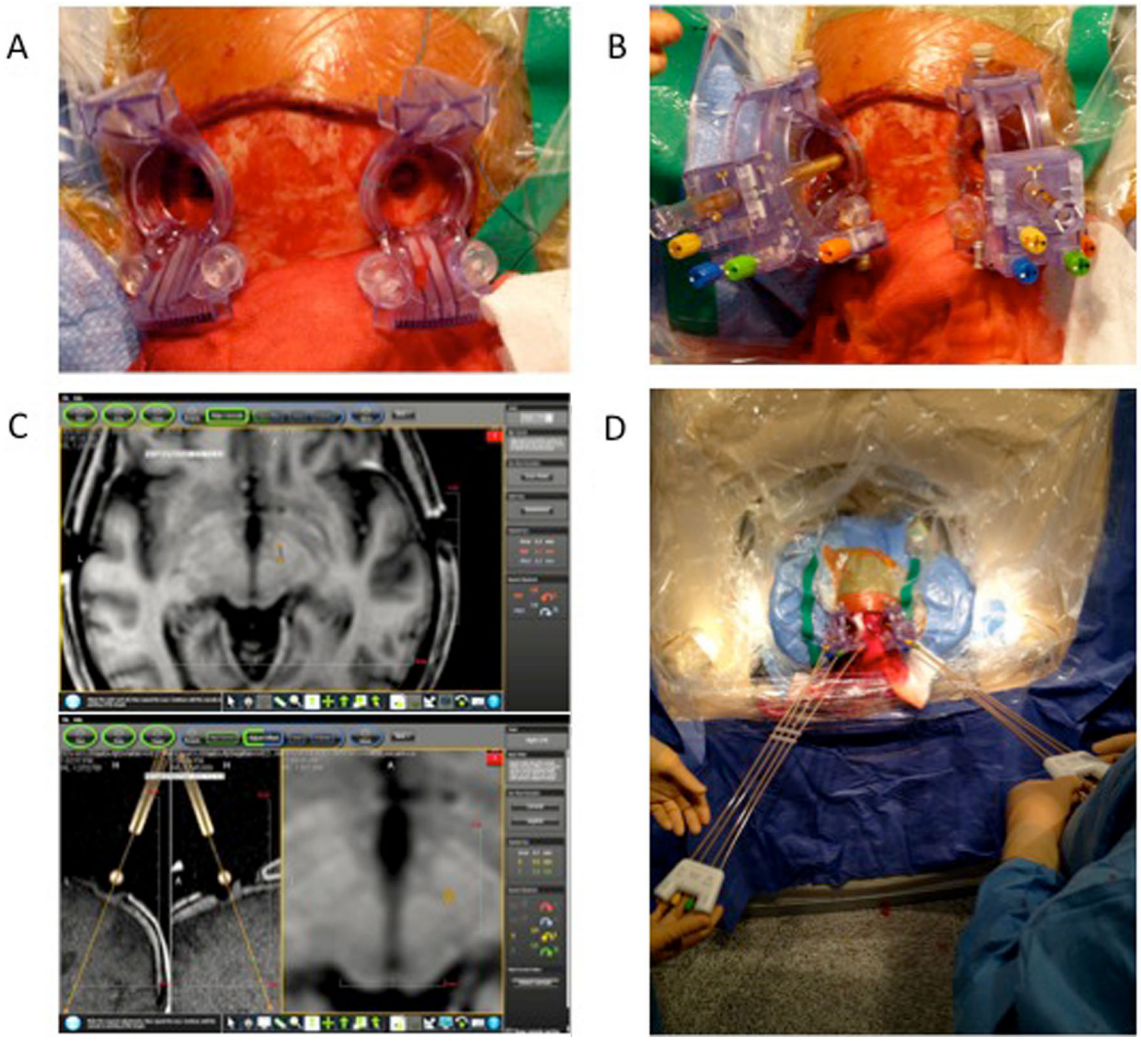

Fig. 3 Fixation and orientation of the SmartFrame. **a**, **b** Two platforms ("SmartFrame") are anchored to the skull bilaterally and a aiming device is mounted on each "SmartFrame" and orientated roughly to the middle of the cranium. **c** A new fast T1 MRI sequence is acquired to align the center of the platform with the trajectory. **d** When needed, the trajectory is modified with a remote system fixed on the ring of the platform, which allows correcting the pitch and roll

controlled during On Stim, which explains the greater improvement of UPDRS during On Stim. Overall, the quality index, defined as the ratio between improvement during On Stim and during baseline reached 63 % in patient 1 and 406 % in patient 2. No cognitive deterioration occurred in both patients as underlined by the MATT IS scale at 1-year follow-up, which was stable as compared to the pre-operative state.

Discussion

We report here our preliminary experience of DBS lead implantation in the STN of two PD patients using intraoperative MRI guidance technique.

Rationale for using intra op MRI guidance

Since the first description of DBS leads implantation technique in the STN by our group in 1993 [13], many authors have reported their own experience that contributed to improve the technique in an attempt to increase accuracy, decrease side effect, and risks while keeping the best ratio of improvement on akinesia, rigidity, and tremor close to that defined preoperatively under suprathreshold dose of levodopa. Originally, the definition of the target was indirect based on atlas, thus multiple tracks [17] had to be done to sample the area with microrecording electrodes to isolate extracellular action potentials that were described as key features of the dorsolateral part of the STN. When this electrophysiological signature was defined, microstimulation was performed on microelectrodes

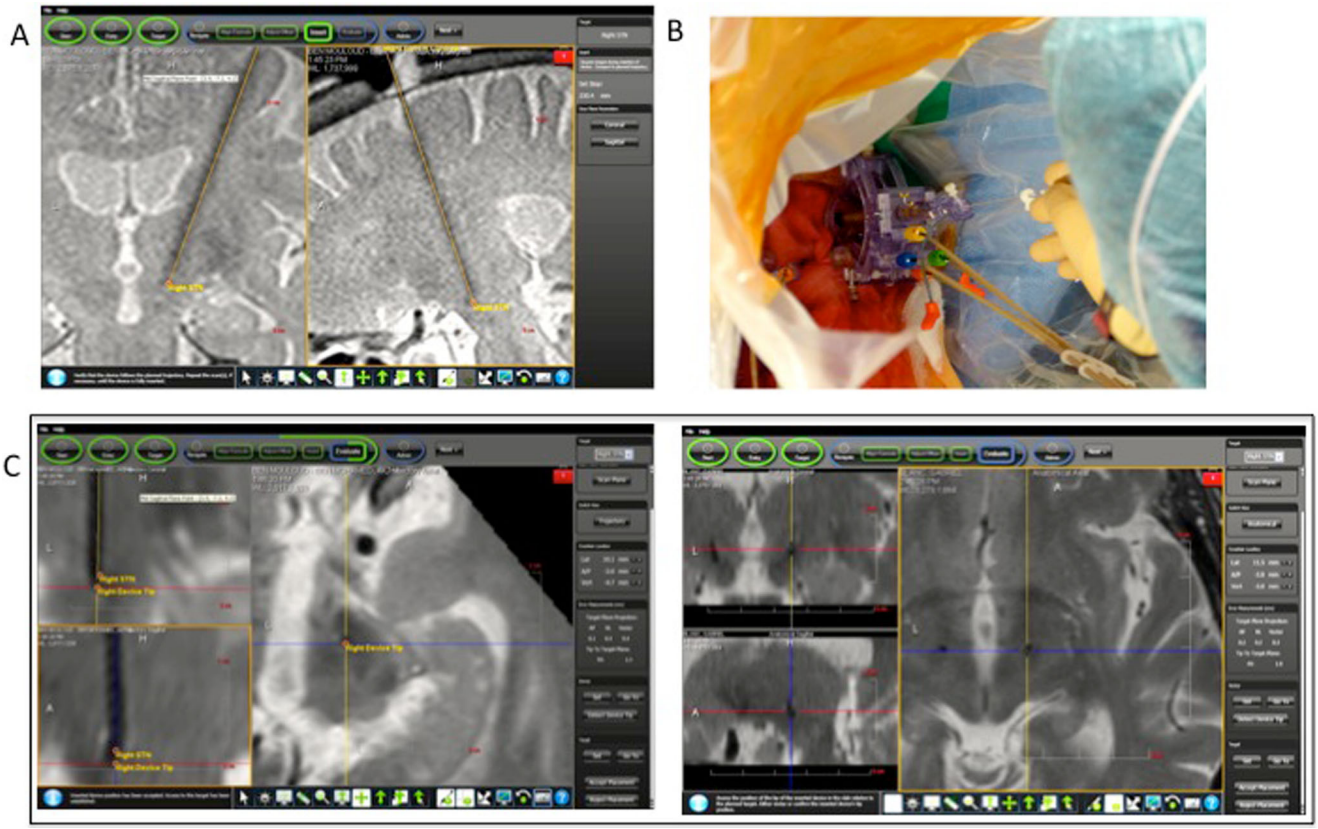

Fig. 4 DBS lead insertion and final MRI sequences. **a** The next step consists of inserting a sharp stylet without opening the dura and a new T1 MRI sequence is acquired to check the trajectory of the stylet. **b** The final step involved the insertion of the chronic lead (3389®, Medtronic, Minneapolis, MN, USA) using a peel-away sheath. **c** Acquisition of new and final T1 MRI sequences (axial) to check the position of the active contact with respect to the target above defined and the absence of any complication

at several levels of the region to asses the threshold of side effects and clinical benefit of the stimulation at least

Table 1 Baseline characteristics

		Patient 1	Patient 2
Sex		Female	Male
Age		71	67
Age at onset		54	55
Symptom at onset		Left upper limb akinesia	Left upper limb tremor
PD duration (years)		17	12
MDS-UPDRS III	OFF	52	42
	ON	22	35
MDS-UPDRS IV			
Dyskinesia	IV.1 (duration)	1	0
	IV.2 (severity)	2	0
Motor fluctuations	IV.3 (duration)	2	1
	IV.4 (severity)	3	1
LEDD (mg/day)		825	750
MATTIS (/144)		104*	137

*Neuropsychological evaluation was performed in French, which was not the mother tongue of the patient. Low educational level

on rigidity and tremor when present. Then many teams postulated that appropriate stereotactic MRI sequences alone let the surgeon to direct localize a structure he previously partly grasped with stereotactic repairs then refined by electrophysiological analysis [26]. They advocated that relative anatomical variability of targets in PD could potentially limit the accuracy of indirect methods of positioning electrodes into the STN but also the globus pallidus [10]. Thus, this opened the way to the direct targeting technique. Indeed, the improvement of MRI sequences allowed to better delineate the shape of the STN and many groups started to describe direct targeting of the STN based solely on direct visualization of it [5, 19, 24]. As the coordinates of optimal target within the STN was reported by many groups, it appears that direct implantation of the lead based only on the anatomo-clinical definition of the target was a reasonable strategy, whereas some authors still used peri-operatory stimulation performed on the final lead (macro stimulation) to check the threshold of side effects. However, as the number of patients implanted worldwide increased, variability in the results of STN-DBS was reported due to several reasons, among them, the lack of accuracy during surgical implantation of the leads. Indeed, in unfavorable cases, post-op

Table 2 Postoperative UPDRS scores, L-DOPA equivalent daily dose (LEDD) and MATTIS score

		Patient 1	Patient 2
UPDRS III	**OFF-med/ON-stim**	**33**	**14**
	OFF-med/OFF-stim	39.5	41
	ON-med/OFF-stim	29.5	27
	ON-med/ON-stim	23.5	12
	Improvement On Med*	57 %	16 %
	Improvement On Stim**	36 %	65 %
	Quality index***	63 %	406 %
UPDRS IV	Dyskin. time IV.1	0	0
	Dyskin. severity IV.2	0	0
	Motor fluct. Time IV.3	1	0
	Motor fluct. severity IV.4	3	0
MATTIS		104	136
LEDD		1200	105

•Improvement ON med = (baseline – ON med)/baseline

•Improvement ON Stim = (baseline - ON stim)/baseline

•improvement ON Stim/ improvement On med

CT or MRI scans revealed "sub-optimal" position of the leads, leading to the impossibility to chronically deliver the proper current to the contacts due to side effects, leading to surgical repositioning of the leads [1]. Among reasons to explain the inaccuracy of lead positions beside errors of targeting due to difficulties to delineate the STN, image fusions errors in a common stereotactic space, distortions of MRI images, mechanical errors of the frame or the ring, and lead deviations were commonly reported. Altogether, these issues led to the development by Starr, Larson, and coworkers, of a new technique using intraoperative MRI guidance allowing to avoid image fusion to check directly the accuracy of lead position and to correct in almost real time any deviation of the trajectory, and finally, would allow to detect any surgical complication such as hematoma. Furthermore, the impossibility or the unwillingness for some patients to tolerate an extended awake surgery have created a need for extending indications of DBS under general anesthesia, with the requirement to monitor as much as possible the accuracy of lead position during surgery.

Table 3 Coordinates of targets and final lead deviation

	Patient 1		Patient 2	
	R STN	L STN	R STN	L STN
TARGET (mm) relative to mid-commissural point	x: -2.0 y: 11.5 z: -3	x: -2.0 y: -11.8 z: -3	x: -2.5 y: 11.0 z: -3.4	x: -2.5 y: -11.0 z: -3.5
Lead deviation (mm) and radial distance at the level of the target	x: 0.2 y: 0.3 d=0.36	x: 0.7 y: 0.5 d=0.86	x: 0.1 y: 0.4 d=0.41	x: 0.1 y: 0.1 d=0.14

Feasibility and technical requirement

Overall, the surgeries went very well with no technical problems. The quality of MRI sequences was good enough to allow direct and indirect targeting of the STN. Lead insertion itself was performed with one single tract. Here we adapted the technique already described by our group using a sharp stylet that avoids opening the dura and limits consequently any cerebrospinal fluid (CSF) leakage.

Inserting DBS leads under high-field (1.5 T) MRI guidance requires several adaptations and equipment. First of all, our operating room (OR) was not equipped with high-field intraoperative MRI and it was necessary to transform our conventional diagnosis MRI suite (Philips scan) into an operative theatre. To that aim, MRI-compatible surgical skills were used, together with MRI-compatible anesthesiological monitors. Second, it was necessary to use dedicated navigation software (ClearPoint system), a trajectory guide platform (SmartFrame), and head coils. The surgery needed the assistance of an engineer from the company (MRI Interventions, Irvine, CA, USA), a neuroradiologist, and an MRI technician, together with an anesthesiologist team. All surgical tools needed to be MRI compatible, including an MRI-compatible drill. The risk of severe injury with the lead inserted into the brain when a 1.5-T MRI scan is performed has been already reported but has to be counterbalanced with the large number of patients in whom MRI scans, using head coils, have been performed also without any problems [4, 6, 16, 25]. While some isolated MR complications occurred in implanted patients, with the need to modify safety rules [7, 9, 21], many teams reported accuracy, innocuousness, and advantages of its use.

Accuracy

The accuracy of the position of the first stylet was checked by measuring the radial distance between the tip of the stylet and the target at its level. A second measure was also collected when the final DBS lead was inserted. In the two patients, the accuracy of lead positioning was very good, (minimum: 0.14 mm, maximum: 0.86 mm) and these results confirmed the accuracy already reported by the UCSF group. According to the literature, which usually reports an accuracy of lead position using frame-based or frameless technique with mean total errors of 2.2 mm and mean lateral errors of 1.7 mm [20, 23], MRI guidance technique appears to add novelty in that field. Of course, our preliminary experience is based only on two case reports but using the technique, Starr and coworkers have reported a total of 29 patients (53 electrodes) with a mean radial error of 1.2±0.65 mm, and a mean absolute tip error of

Table 4 Chronic parameters of stimulation and threshold for stimulation-induced side effects

	Patient 1		Patient 2	
Stimulation parameters	R-STN	L-STN	R-STN	L-STN
Contact	2-	11-	2-	10-
Amplitude (V)	2	2	3.2	2.8
Rate (Hz)	130	130	150	150
Pulse width (μs)	60	60	60	60
Side effects threshold	▪ 5.0 V transient paresthesias ▪ 5.5 V contralateral chin contraction	▪ 3.0 V transient paresthesias ▪ 4.0 V monocular ipsilateral deviation	▪ 3.5 V transient paresthesias ▪ 5.0 V heating sensation	▪ >3.0 V transient paresthesias

2.2±0.92 mm. We used the same MRI scan (Philips, 1.5 TESLA, Achieva®) but results may vary slightly according to the type of MRI machine and this will have to be assessed in future studies. Also, we did not open the dura, and consequently we did not have to take into account any brain shift, which may have minimized the risk of lead deviation. Finally, the clinical outcome at 1 year was in the range of what we usually obtain using a robotic-guided technique in our patients in routine, but due to the small numbers of patients in our experience with MRI guidance, and the lack of any design allowing comparison, it is difficult to shed light on the advantages and disadvantages of the two techniques.

Clinical advantage and pitfalls

As with all surgical techniques, there are some pros and cons that need to be challenged to establish the best balance. The MRI guidance technique is an appealing one, with dedicated software and tools that made the surgery reasonably easy even for the first cases. One of the major advantages to be put to the credit of MRI guidance technique is the possibility of obtaining the MRI scan in almost real time, using a single referential space (the isocenter of the magnet), avoiding the use of frame and images fusions. This allows to save time, discomfort for the patient, and obtaining very good accuracy. The two patients expressed a high level of satisfaction with this technique, probably due to the fact that they were operated on under general anesthesia, which is mandatory for this technique. Due to the severity of her clinical condition, patient 2 was not capable of undergoing surgery under local anesthesia and refused surgery for many years. The choice offered to her to be operated on under general anesthesia, using the MRI guidance technique, finally helped her to decide for the operation. MRI-guided surgery does not allow any microrecording, and in fact was designed in some aspects to avoid it. Replacing electrophysiological by radiological monitoring during surgery may be seen as a potential benefit for the patient as it has been reported that micro-electrode recordings could carry some additional risks of hemorrhages [8, 12]. However, electrophysiological recordings also have many advantages when performed rigorously, and indeed this technique is the only one allowing direct observation of dysfunction of the STN, a key feature of the disease.

MRI guidance technique does not yet allow to stimulate during surgery to check the threshold of motor contraction and eye deviation, which can be done under general anesthesia but outside the magnet. Consequently, the risk of sub-optimal position of the lead does still exist, but is minimized due to direct visualization of the contacts inserted within the STN, and the very good accuracy of the system. Adding diffusion tensor imaging DTI sequences could definitively increase the benefit of this technique.

Paradoxically, one of the disadvantages is the need to have access to the MRI facility for many hours, which can be an issue in the context of an over-charged agenda for MRI diagnosis. We operated on one patient on Saturday to limit the impact of surgery on the MRI suite organization, but that cannot be routinely repeated, at least, at our institution. Of course, having an MRI in a regular OR that could be used for DBS lead implantation is another option, which is in fact limited to few centers in the world.

Conclusions

Frameless stereotactic procedures with intraoperative MR guidance appears to be safe and efficient in series already reported with a presumed gain in accuracy. This strategy is promising and could be used when deep brain stimulation electrodes have to be implanted under general anesthesia. Intraoperative monitoring of anatomical lead location could replace intraoperative MER, but post-operative clinical improvement will have to be assessed, especially for STN surgery in larger cohorts. The dissemination of this technique, even promising, will depend on the dissemination of intraoperative MRI suites or on the facilitation of access to regular-diagnosis MRI suite to perform interventional MRI.

Conflict of interest None.

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