Deep Brain Stimulation : Can O-arm Imaging Replace Intraoperative Clinical Examination?

Travail de Maîtrise de Michael Ris Dirigé Par Pre. Jocelyne Bloch

This work is essentially focused on Parkinson’s disease and Essential Tremor because these patients benefit the most from DBS. The goal of this work is to investigate if DBS can be performed under general anesthesia by using the O-arm imaging (intraoperative CT) as the sole technique for electrode positioning.

Special thanks to: Professore Jocelyne Bloch and Professor Joseph-André Ghika

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INTRODUCTION

Deep Brain Stimulation (DBS) is a surgical treatment offered to a limited number of patients, generally suffering from movement disorders, but also from neuropathic pain, epilepsy or chronic psychiatric diseases. To obtain a therapeutic effect, it is essential to precisely implant the electrode in a chosen nucleus of the brain. For the present work, we mainly focus on Parkinson's disease and Essential Tremor because they represent the most frequent indications for deep brain stimulation

Idiopathic Parkinson is a disease which affects people with an average age of 60 years. Its prevalence is around 3/1000 people. James Parkinson described for the first time the symptoms of this disease in 1817. Even if we have been knowing this pathology for 200 years, it's origin still remains unclear in most of the cases ([1,2]). Among all the features the disease, there is a dopaminergic neuronal degeneration in the Substancia Nigra Pars Compacta leading to a dysfunction of the extrapyramidal pathways. The lack of dopamine mainly compromises the putamen, the caudate nucleus, the pallidum and the subthalamic nucleus ([3]). The cardinal signs of Parkinson's disease are:

- Akinesia: a spontaneous delayed and slow voluntary movement but with normal force, visible during walking, writing and talking.
- Rigidity: increased tonic resistance to muscle elongation sometimes with cogwheel phenomenon when underlying tremor is present.
- Parkinson Tremor: a slow, low amplitude, unilateral and successively bilateral tremor at resting ([4]).

The four main drugs used in Parkinson's disease are L-dopa, dopaminergic agonists, dopamine metabolic inhibitors and anticholinergic. These drugs are given to increase the cerebral dopamine level and to normalize the dopamine/ acetylcholine ratio ([4]).

A subgroup of patients (5-10%) will exhibit very disabling untreatable motor fluctuations such as unpredictable blocking phases followed by dyskinesia. This occurs generally after a few years of disease evolution despite optimal medical treatment. In those situations, DBS surgery is proposed.

The indication for DBS includes ([5]):

- Idiopathic Parkinson with at least 5 years of evolution
- Severe and disabling motor fluctuations for more than 6 months despite optimal adjusted drug therapy or unsustainable secondary drug side effects
- A good Dopamine sensitivity (> 30% improvement in motor score)
- Severe side effect of medication despite good sensitivity to dopamine

Contraindications of DBS surgery include ([5]):

- Dementia or uncontrolled psychiatric disease
- Encephalic anatomical abnormalities which carry a higher risk of hemorrhage
- Other pathologies that compromise the lifetime of the patients or their survival after surgery.

Relative contraindications include ([5]):

- Patients older than 75 years
- Static signs without improvement with L-Dopa

The final decision to implant an electrode in the subthalamic nucleus or the pallidum is discussed at a multidisciplinary board including neurosurgeons, neurologists, psychiatrists and neuropsychologists ([5]). Preoperative assessment include:

- A test with a supra-maximal dose of Levodopa administration showing more than 30% improvement in motor score proving dopa-sensitivity. Clinical scoring is applied for drug efficiency quantification such as the Movement Disorder Society Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) or the Essential Tremor Rating Scale (ETRS)
- A global psychological and neuropsychological evaluation of the patient
- MRI imaging with T1 gadolinium injected sequence and T2 space sequence to exclude neurosurgical contraindications and to plan DBS surgery
- A general health condition and comorbidity evaluation of the patient

Essential Tremor is a postural and action tremor slightly faster than parkinsonian Tremor (5-7 Hz) presents during maintenance of postures and on action with final intentional tremor near the target, which is most disabling in daily life activity ([6]). The prevalence of Essential Tremor is difficult to estimate due to the variability of its clinical presentation ranging from slight to very severe symptoms. However, it is believed that Essential Tremor is the most common movement disorder ([7]). The age of onset can be either adolescence or around the 5-6th decade, and half of the patients have a hereditary (autosomal dominant) disease whose genetics is still to be discover, probably because age-related tremor has been mixed with real essential tremor in most studies ([7]). The initial symptoms usually include a postural tremor in the hands, which may later expand and involve the head and other parts of the body. Typically, the tremor amplitude increases and its frequency decreases with age and duration of the disease. Disability results from impairment of fine motor skills and social isolation ([7]). Pharmacological treatments include the administration of alcohol, β-adrenergic-blockers, primidone, phenobarbital, benzodiazepines, anectotal effects have been reported with levetiracetam and topiramate. First line treatment usually consists of β-adrenergic-blocker administration ([7,8]). If medical treatment becomes inefficient or is associated with important side effects, DBS surgery may be indicated. The target for DBS is the ventro-intermedialis nucleus (VIM) of the thalamus, however, in contrast to the sub-thalamic nucleus which is clearly visible on MRI, the VIM is not identifiable within the thalamus by classical imaging. Therefore, indirect targeting of the VIM during DBS is required which is based on atlas coordinates.

The indications for DBS in Essential Tremor are ([5]):

- Essential Tremor with confirmed highly suspected diagnosis
- Severe and invalidating symptoms despite optimal medical therapy with at least two different treatment lines
- No contraindication for surgery

Contraindications for DBS in ET include:

- Dementia or uncontrolled psychiatric disease

- Encephalic anatomical abnormalities which carry a higher risk of hemorrhage
- Other pathologies that compromise the lifetime of the patients or their survival after surgery

At CHUV, DBS procedures are performed under local anesthesia. This allows for the evaluation of the stimulation during surgery. The neurologist performs a neurologic examination during the stimulation phase to test the efficacy of DBS and its side effects. Depending on the clinical results, the location of the electrode can be adjusted through another track. However, nowadays other tools are available during surgery to decipher the precise location of the implanted electrode. At CHUV, we use the O-arm which consists of a mobile operative CT scan which allows in addition the fusion with the preoperative MRI. This enables a precise location of the implanted electrode which can then be compared to its planned trajectory. Depending on this analysis, a readjustment of the implantation site can be performed if required. However, the final decision of repositioning an electrode or leaving it in place will depend on the neurological examination during the procedure. The aim of the present work is to correlate the clinical results obtained during the perioperative neurological examination with the position of the electrode observed on O-arm / MRI imaging. A high correlation between O-arm imaging and clinical examination findings may allow the switch from local to general anesthesia for the realization of the procedure, with increased safety and comfort to our patients.

MATERIAL AND METHODS

In order to assess the correlation of O-arm imagery and per-operative clinical examination during DBS, we prospectively collected clinical and radiological data of patients undergoing DBS from September 2015 to September 2017 at our institution. We designed a study protocol in which the neurologists performing the clinical per-operative assessment were blinded to the radiological results driving from O-arm imaging.

In a first phase, the neurosurgeon compared the per-operative O-arm images to the location of the electrode with its planned trajectory. Depending on the imaging result, the neurosurgeon decided either to leave the electrode in place if its location perfectly matched the planned trajectory, or to adjust its position to a more appropriate location in order to approach the planned target. If an adjustment was necessary, it could be realized in 8 different directions (anterior, posterior, lateral, medial, antero-medial, antero-lateral, postero-medial or postero-lateral). In a second phase, the neurologist who was blinded to the position of the electrode, performed a neurological exam. Depending on the response obtained during the stimulation, he might suggest to change it according to one of the eight directions mentioned above. The clinical findings emerging from the neurological exam were then compared with per-operative O-arm imaging keeping in mind that the clinical evaluation had more importance on the final position of the electrode.

STUDIED POPULATION

The indications for DBS surgery in Parkinson and essential tremor patients followed the one described in the introduction.

SURGICAL PROCEDURE OF DBS AT CHUV

1) For Parkinson's disease, the patient is hospitalized 48 hours before surgery and the medical treatment is progressively stopped. For

essential tremor, the patient is hospitalized 24 hours before surgery without medical treatment cessation.

2) The morning of the surgery, a CRW stereotactic frame is fixed on the head of the patient under local anesthesia.

3) A 3D CTscan is performed with the stereotactic frame in place.

4) The surgical planning is performed by use of the Medtronic Stealthstation and was based on the stereotactic CT scan imaging and 2 sequences of 3D MRI images obtained prior to surgery (MPRAGE Gado + Space T2). For Parkison's disease, the subthalamic nucleus (STN) was visualized and for Essential Tremor, the ventro-intermedialis nucleus (Vim) is indirectly targeted. The trajectory of the electrodes is the planned and entered the coronal suture region while avoiding vessels, sulcus and ventricles. In the operation room, the patient is then positioned in the supine position and the head is fixed to the operating table with the stereotactic frame. The surgery generally starts on the most affected side. A local anesthesia is performed at the entry point located around 3 to 4 cm lateral to the midline and close to the coronal suture and a "U" shape skin incision was performed. A 8mm burr hole is then stereotactically performed. A micro electrode is inserted 8mm above the target through the central track of the Ben Gun device, a stereotactic tool which allows the positioning of the electrode near the target through 5 different parallel tracks (See protocol and figure in annex).

5) *Micro recording:*

   This micro recording is mainly explored for Parkinson's disease since it allows the identification of the STN. The high frequency firing rate of the STN compared to the adjacent structures allows us to define the borders of this nucleus. ([9])

6) *O-arm imaging:*

   This technique allows the acquisition of a per-operative 3D CTscan imaging and is capable of merging the intraoperative 3D CT-scan imaging with the preoperative stereotactic CTscan and the 3D IRM usually performed one month before the intervention. This merging procedure allows us to match the peroperative localization of the electrode and the planned trajectory. In general, a discrepancy of one millimeter is acceptable. Otherwise a new track is tried toward the planned trajectory.

7) *Macrostimulation:*

After placement of the electrode, the neurologist performs a clinical examination. The microelectrode is replaced by the stimulation electrode and macrostimulation is started from 6mm above the target down to the target. Three stimulation frequencies are tested (2, 50 and 200 Hz) at different localizations and current intensities. Face, upper limb or lower limb contractions at 2 Hz indicated that the electrode is located too close to the internal capsule. A worsening of the symptomatology is expected at 50 Hz. At 200 Hz which corresponded to the therapeutically frequency, an improvement of the clinical signs is expected with release of the rigidity, improvement of the bradykynesia and/or stop of the tremor. With increased stimulation intensity, appearance of secondary effects is generally observed. If the margin between the therapeutic effect and the adverse effects is to small when increasing the intensity of stimulation, it normally indicates that the electrode is not ideally placed.

8) After satisfactory placement of the electrode, the definitive electrode is inserted (Medtronic Activa 3389 for STN and Medtronic Activa 3387 for Vim) after removing the temporary electrode.

9) *O-arm image acquisition:*

A second O-arm image acquisition is then obtained to check the definitive placement of the final electrode.

10) *Fixation of the electrode:*

The definitive electrode is fixed to the skull with cement. The same procedure is generally performed on the other side.

11) *Implantation of the neurostimulator:*

At the end of the implantation procedure, the skin is closed and the stereotactic frame is removed.

12) A final O-arm imaging is performed to check the final position of the electrodes and to exclude a hemorrhagic complication. On post-operative day 1-3, extension cables and programmable batteries are

implanted under general anesthesia, usually in subclavicular regions by tunneling extension cables.

DATA COLLECTION AND ANALYSIS

The first part of the study protocol was filled out by the neurosurgeon (see annex), who made a suggestion following the result of the O-arm. Should the electrode stay in place or should it be replaced.

The second part of the protocol was filled out by the neurologist, he made a proposition (stay in place or move) based on his clinical examination. Both propositions were then compared and a final decision was taken between neurosurgeon and neurologist.

Data collection was performed by Pre. Jocelyne Bloch or Michael Ris according to the protocol after DBS (see annex). According to those data collection, a table was dressed with all the essential results in order to compare the precision of O-arm imagery and the intraoperative clinical examination for PD and ET.

RESULTS

We performed bilateral DBS in 20 patients with a total of 40 electrodes being definitely implanted into the subthalamic nucleus or the ventro-intermedialis nucleus, respectively. According to the recommendations derived from the literature, the results obtained from Parkinson and Essential Tremor DBS were separately treated and discussed.

We performed DBS in 13 Parkinson patients with implantation of a total of 26 electrodes in the subthalamic nucleus. This group of patients consisted of 10 men and 3 women with a mean age of 62.9 years ranging from 43 to 74 years (Table 1). DBS for Essential Tremor was performed on 7 patients with implantation of a total of 14 electrodes in the ventro-intermedialis thalamic nucleus, 4 men and 3 women with a mean age of 60.1 years (range 29-78 years), (Table 2).

Table 1 and 2 summarize the data collected during the interventions. We focused on the correlation between the originally calculated trajectory of the implanted electrodes and their definitive position chosen during the operation according to O-arm imaging and intraoperative clinical examination. In three patients, we explored a new trajectory but decided then to keep the initial trajectory because the initial one was related with a better clinical response and less side effects (indicated as ‘’No, first better’’ in Tables 1 and 2). In one case, the clinical examination suggested a more posterior trajectory but the imaging showed that this was too risky for anatomical reasons (indicated as ‘’No, too risky’’ in Tables 1). In these two kinds of situations, we interpreted the results emerging from clinical examination and O-arm imaging as concordant since the first trajectory remained the definitive one.

Two clinical relevant findings can be observed; *a),* the number of secondary trajectories required to obtain a satisfactory result and *b),* whether the final positioning was rather obtained from O-arm imaging or from intraoperative clinical examination.

In the column *Imaging* we have a sub-column entitled “Less than 1mm” meaning that target was found by the first trajectory attempt while accepting a distance of 1mm to the target on O-arm imaging provided that there were no major side effects observed during the clinical examination. In the sub-column entitled “More than 1mm”, the neurosurgeon considered a new trajectory to approach more precisely the target. In the column entitled “Clinical examination”, the neurologist observed either a good clinical response with minor side effects or suggested a new electrode trajectory. The last column entitled ‘’Final Trajectory tract’’ contains the final Ben Gun tract while *police in red* indicates that the final tract differs from the initial one. Furthermore, the term “concord” was used to demonstrate a concordance between O-arm imaging and clinical examination.

TABLE 1 : DBS FOR PD IN 13 PATIENTS WITH IMPLANTATION OF 26 ELECTRODES

N°Patient :	Age	Sex	Target	Imaging		Clinical Examination	Final trajectory tract
				≤ 1 mm	≥ 1 mm	Good therapic response vs modification suggestion	
1. First side	60	Male	STN	1 mm anterior		Good response	Central & Concord
1. Second side	60	Male	STN		electrode is : 2 mm medial + 2mm anterior	new suggestion : Lateral	Postero-lateral & Concord
2. First side	72	Male	STN	0 mm		Good response	Central & Concord
2. Second side	72	Male	STN	0 mm		Good response	Central & Concord
3. First side	66	Female	STN	0 mm		Good response	Central & Concord
3. Second side	66	Female	STN	0 mm		Good response	Central & Concord
4. First side	67	Male	STN	0 mm		Good response	Central & Concord
4. Second side	67	Male	STN	1 mm anterior + 1 mm medial		Good response	Central & Concord
5. First side	74	Male	STN	0 mm		Good response	Central & Concord
5. Second side	74	Male	STN	0 mm		new suggestion : Posterior	No, too risky
6. First side	50	Male	STN	1 mm medial		Good response	Central & Concord
6. Second side	50	Male	STN		electrode is : 1 mm lateral	new suggestion : Postero-medial	Postero-medial
7. First side	54	Male	STN	0 mm		Good response	Central & Concord
7. Second side	54	Male	STN	0 mm		Good response	Central & Concord
8. First side	62	Female	STN		electrode is : 2 mm medial + 1 mm posterior	new suggestion : Postero-lateral	postero-lateral & Concord
8. Second side	62	Female	STN	1 mm medial		Good response	Central & Concord
9. First side	70	Male	STN	1 mm lateral		Good response	Central & Concord
9. Second side	70	Male	STN	0 mm		Good response	Central & Concord
10. First side	67	Male	STN	0 mm		Good response	Central & Concord
10. Second side	67	Male	STN	0 mm		Good response	Central & Concord
11. First side	43	Male	STN	0 mm		Good response	Central & Concord
11. Second side	43	Male	STN	1 mm lateral		new suggestion : Postero-lateral	No, first better
12. First side	66	Male	STN	0 mm		Good response	Central & Concord
12. Second side	66	Male	STN	1 mm posterior		Good response	Central & Concord
13. First side	67	Female	STN	1 mm lateral		Good response	Central & Concord
13. second side	67	Female	STN	1 mm lateral		Good response	Central & Concord
Mean age [years]	62.92						

TABLE 2 : DBS IN 7 PATIENTS WITH ET AND IMPLANTATION OF 14 ELECTRODES

N°Patient :	Age	Sex	Target	Imaging		Clinical Exam	Final trajectory tract
				≤ 1 mm	≥ 1 mm	Good therapic response vs modification suggestion	
1. First side	78	Female	Vim	1 mm lateral		Good response	Central & Concord
1. Second side	78	Female	Vim	1 mm anterior		Good response(If change, anterior-medial)	Central & Concord (No change)
2. First side	52	Female	Vim	1 mm medial		Good response	Central & Concord
2. Second side	52	Female	Vim	0 mm		new suggestion : Antero-medial	Antero-medial
3. First side	69	Female	Vim	0 mm		new suggestion : Postero-medial	Postero-medial
3. Second side	69	Female	Vim		electrode is : >1 mm anterior	new suggestion : Posterior	Posterior & concord
4. First Side	71	Male	Vim		electrode is : >1 mm anterior	new suggestion : Postero-medial	Postero-medial & concord
4. Second side	71	Male	Vim		electrode is : >1 mm anterior	new suggestion : medial	Postero-medial & concord
5. First side	29	Female	Vim	0 mm		new suggestion : Postero-medial	Postero-medial
5. Second side	29	Female	Vim	0 mm		Good response	Central & Concord
6. First side	73	Male	Vim	0 mm		new suggestion : Postero-lateral	No, first better
6. Second side	73	Male	Vim	1 mm posterior		Good response	Central & Concord
7. First side	49	Male	Vim	1 mm posterior		Good response	Central & Concord
7. Second side	49	Male	Vim	0.5 mm medial		new suggestion : Anterior	No, first better
Mean age [years]	60.14						

DBS for Parkinson's disease: From 26 implanted electrodes, three (11.5%) required a repositioning, one on the first operated side and two on the second one. Two of them (7.7%) revealed again a concordance of O-arm findings and clinical examination during the secondary electrode positioning. In one repositioning (3.84%), there was a discordance between the clinical exam and O-arm imaging. Overall, for PD, there was a concordance of O-arm findings and intraoperative clinical examination in 25/26 electrode trajectory placements (96.15%), only one electrode was guided only by the clinical examination.

DBS for essential tremor**:** From 14 electrode trajectory placements, 8 (57.14%) revealed a concordance between O-arm imaging and neurological exam at the first positioning attempt. Six (42.86%) required a trajectory repositioning and 3 of them (21.43%) revealed again a concordance of O-arm and clinical findings. A discordance between the clinical exam and O-arm imaging was found in 3 electrodes repositioning (21.43%). Overall, for ET there was a concordance of O-arm imaging and clinical findings in 11/14 electrode trajectory placements (78.57%), there were 4 electrodes which were guided only trough the clinical examination.

DISCUSSION

Our results indicate that for PD, there was a concordance of O-arm findings and intraoperative clinical examination in 96.15% of electrode trajectory placements. However, for ET, there was a concordance of O-arm imaging and clinical findings in only 78.6% of electrode trajectory placements while 21.4% of definitive electrode placements were guided solely by clinical examination.

This discrepancy between the results obtained for PD and ET can be in part explained by the fact that the STN, the target of DBS in PD, is a distinct anatomical structure which can be clearly identified during preoperative DBS assessment and planning. This is not the case for ET since the VIM, the target of DBS in ET, is anatomically less well defined and stereotactic calculation is mandatory in addition to stereotactic mapping for its identification.

Our results suggest a surprisingly good correlation between O-arm imaging and clinical examination which questions the paradigm that intraoperative clinical examination is essential for DBS, at least for PD. In fact, our results indicate that for PD, O-arm imaging might be sufficient allowing the realization of the procedure under general anesthesia. Other groups have already taken this decision such as the group of London, where STN-DBS is performed under general anesthesia with an intraoperative IRM to confirm the position of the electrodes ([10]). In addition, the surgical equipment has considerably improved with the introduction of new multidirectional electrodes (capable to adapt the stimulation field in the targeted brain area and to correct an eventual imprecision of the electrode positioning in the postoperative period ([10]).

However, for ET, it would be premature to implement O-arm imaging as the unique tool to guide the electrode positioning and to perform DBS under general anesthesia while avoiding a clinical examination. Since a substantial number of electrodes were finally placed based on the findings from clinical examination.

Finally, the number of our sample size is rather small with 13 and 7 PD and ET patients, respectively. However, the substantial difference found between

ET and PD endorses our impression that O-arm dependent electrode positioning is a reliable and valid tool for direct targeting of the STN. For these reasons, the decision to rely entirely on O-arm imaging, could be proposed for STN targeting if required or on patient’s demand. Therefore, the final decision should be individualized and should implicate the patient in the decision process. In contrast, for DBS in ET, we believe that the clinical examination is so far the golden standard since it allows for an optimal precision of the electrode positioning.

In conclusion, for DBS in patients with Parkinson’s disease, a high concordance was found between intraoperative O-arm imaging and clinical examination for the guidance of electrode trajectory positioning. However, this holds not true for DBS in patients with Essential Tremor where intraoperative clinical examination remains essential. For these reasons, the decision to rely entirely on O-arm imaging should be individualized and should implicate the patient in the decision process.

Personal benefits

This work over 3 years, gave me a better idea of how to conceive clinical research and how to try to answer scientifically a clinical question. It allowed me to perceive the time which is required to perform even a relatively small clinical study dealing with a well circumscribed topic as well as all the challenges related to its realization. Interestingly, the results finally obtained have not been foreseen at the beginning of the study. This explains to me the multitude of publications actually available, each of them performed with the idea to improve patient care in a very specific domain.

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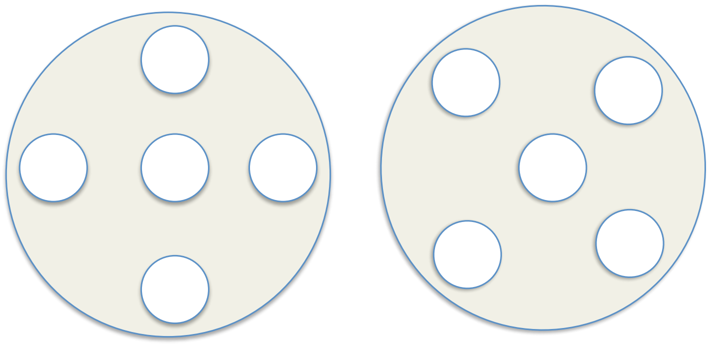
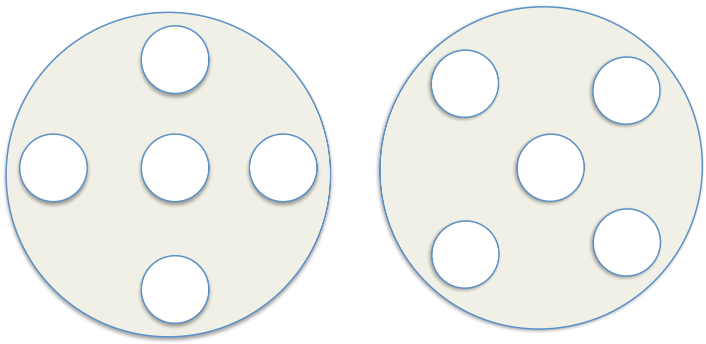
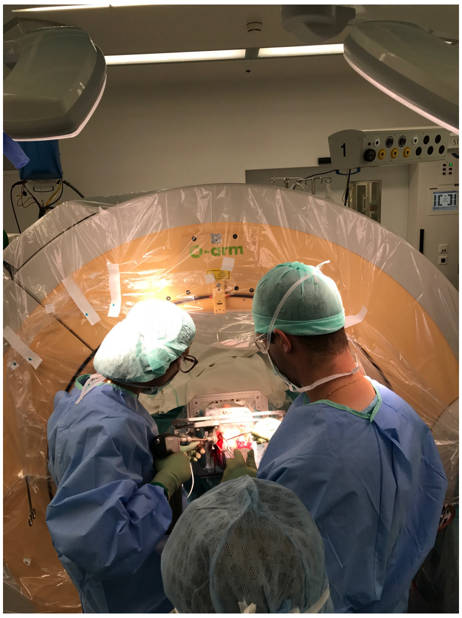
Annexe :

PROTOCOLE OPÉRATOIRE POUR DEEP BRAIN STIMULATION TRAVAIL DE MASTER DIRIGÉ PAR DR. J. BLOCH PD-MER

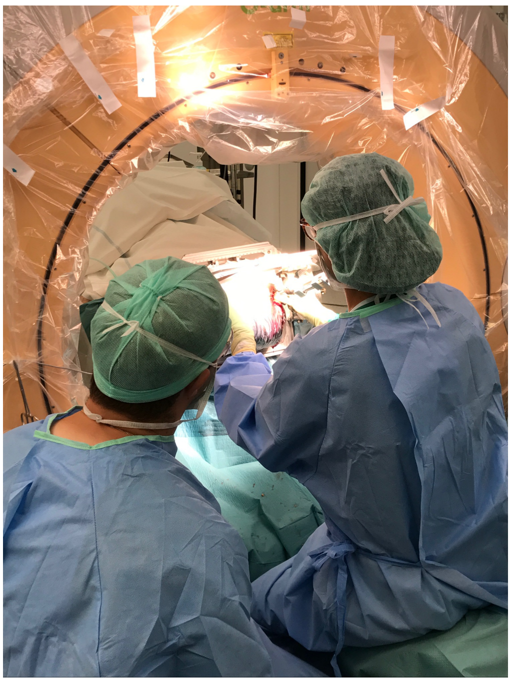
Date opératoire :	**Nom du patient :** **IPP :** **Age :** **Sexe :**
Localisation électrode **Fusion O-arm**	
1ère coordonnée	
1er Examen Clinique	
2ème Trajectoire **« Neurologue »**	
2ème Examen clinique	
2ème coordonnée	
3èmeTrajectoire **« neurochirurgien »**	

3ème Examen Clinique	
Contrôle coordonnée O-arm	

1. The patient enters the operation room, is installed and gets his local anesthesia

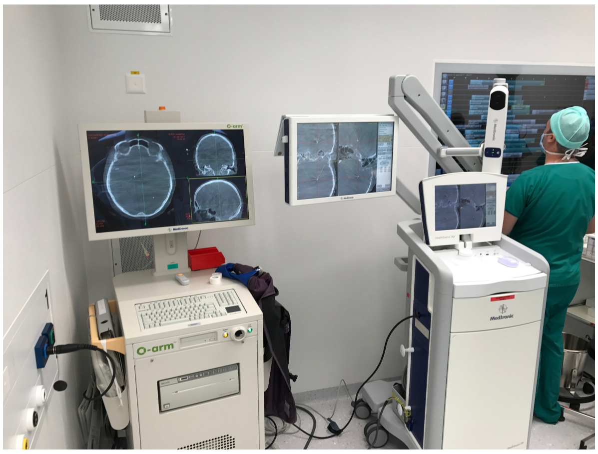


2. The U-inscision is made, and the 2 holes are made.

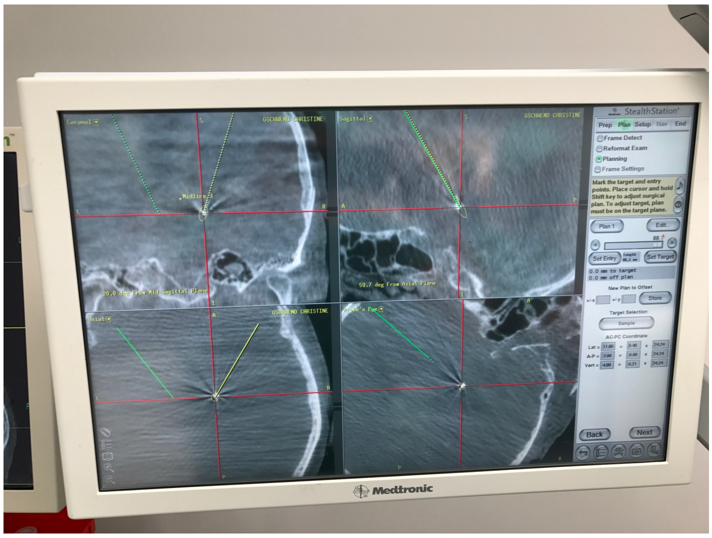


3. The first electrode is introduced in the brain and we can start the micro-recording.

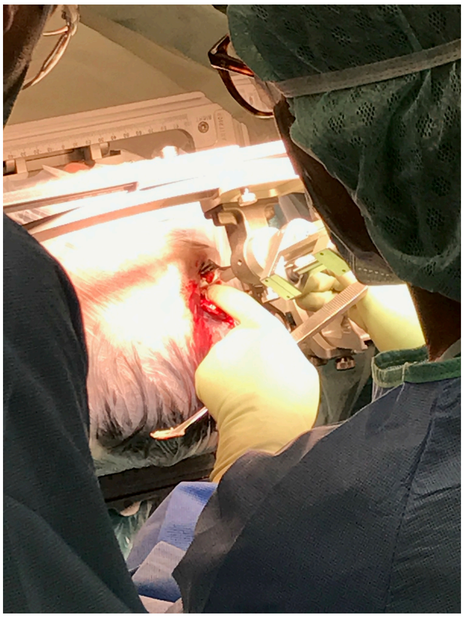
4. The computer shows the spontaneous firing (neuronal noise) of the encountered cells, which are recorded. We are looking for TREMOR CELLS !

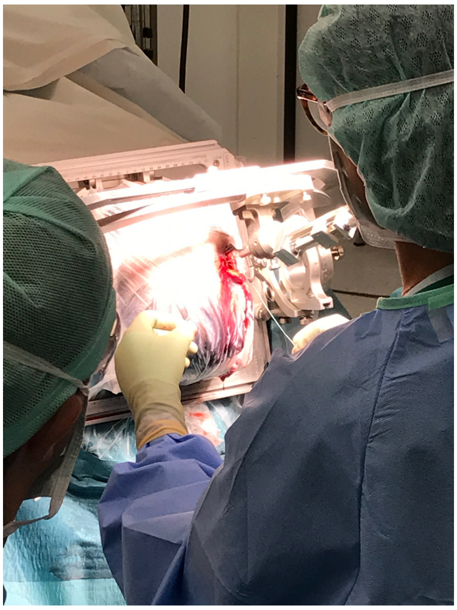


5. The O-arm imaging and the merging procedure to verify the localization of the first electrode.

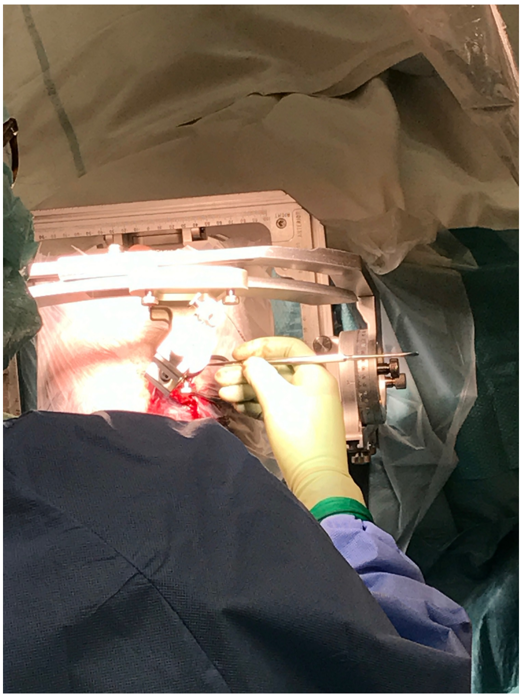


6. The clinical examination by the Neurologist : it's important to see the arm and the leg of the contralateral side of the hemisphere who's operated, to detect the increasing / dimishing of the tremor / rigidity.





7. Once the final tract is in place, and that we verified the localization with imagery, the Neurosurgeon fixes the electrodes to the bone and closes the hole with the cement. When the cement is dry and solid we can make the provisory stiches.
We can start the other side.



8. Once both side done, we do a last verification with the O-arm to ensure that nothing has moved.