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Installation of a Neuromate Robot for Stereotactic Surgery: Efforts to Conform to Japanese Specifications and an Approach for Clinical Use—Technical Notes

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Abstract

The neuromate is a commercially available, image-guided robotic system for use in stereotactic surgery and is employed in Europe and North America. In June 2015, this device was approved in accordance with the Pharmaceutical Affairs Law in Japan. The neuromate can be specified to a wide range of stereotactic procedures in Japan. The stereotactic X-ray system, developed by a Japanese manufacturer, is normally attached to the operating table that provides lateral and anteroposterior images to verify the positions of the recording electrodes. The neuromate is designed to be used with the patient in the supine position on a flat operating table. In Japan, deep brain stimulation surgery is widely performed with the patient's head positioned upward so as to minimize cerebrospinal fluid leakage. The robot base where the patient's head is fixed has an adaptation for a tilted head position (by 25 degrees) to accommodate the operating table at proper angle to hold the patient's upper body. After these modifications, the accuracy of neuromate localization was examined on a computed tomography phantom preparation, showing that the root mean square error was 0.12 ± 0.10 mm. In our hospital, robotic surgeries, such as those using the Da Vinci system or neuromate, require operative guidelines directed by the Medical Risk Management Office and Biomedical Research and Innovation Office. These guidelines include directions for use, procedural manuals, and training courses.

Key words: robotic surgery, stereotactic surgery, localization accuracy, deep brain stimulation, movement disorder

Introduction

The neuromate® (Renishaw Mayfield SA, Nyon, Switzerland) is an image-guided, computer-controlled robotic system that is specifically designed for stereotactic surgical applications (Fig. 1).[1)] This robot system is effective in reducing human errors and operative time.[2)] The neuromate is marked by the Conformité Européene (CE; Europe) for stereotactic applications and neuroendoscopy and cleared by the Food and Drug Administration (FDA; USA) for use in stereotactic procedures. The neuromate was once introduced for use in biopsies and hematoma aspiration procedures in Japan in mid-1990s[3)] and the latest version was approved according to the Pharmaceutical Affairs Law in June 2014.

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The neuromate includes a five degree-of-freedom robotic arm assembly and personal computer (PC)-based kinematic positioning software system. The planning software (VoXim™, IVS Technology GmbH, Chemnitz, Germany) allows for precise image-based planning and in the visualization of multiple trajectories. The robotic system includes safety features in terms of software and hardware, such as tools for follow-up. For example, the arm kinesics control software program can be used to define a zone around the patient's head where the robot arm reduces its speed for safety. With respect to the hardware, there is a mechanism for preventing malfunction of the robotic arm. In addition, the VoXim software package can be employed to set the user-defined safety volume where the robot arm is not allowed to enter, and the robot arm control software program continuously monitors the motion

Fig. 1 The left photograph shows the neuromate robot system, including the five degree-of-freedom robotic arm assembly and personal computer-based kinematic positioning software system. The right photograph shows clinical preoperative planning image that was produced by the planning software (VoXim™, IVS Technology GmbH) at North Bristol National Health Service Trust Southmead Hospital in England.

of the five joints and terminates their movement upon sensing an error of more than 0.15 degrees compared with the planned degree of joint motion, using encoders.

The robot helps to ensure that the burr hole is accurately positioned and oriented, centered on the trajectory axis. The trajectory orientation is not restricted in the way as observed with conventional stereotactic frames, since the robotic arm offers up to four configurations to guide the surgery tools with a suitable orientation.

Japan has a long history of stereotactic surgery, since Professor Narabayashi first developed stereotactic devices and performed the initial pallidotomy procedure using procaine oil in 1952.[4] Stereotactic surgical procedures used in Japan may have developed, to some extent, in different ways from that noted in Europe. For example, the frame-based stereotactic X-ray system developed by a Japanese manufacturer (Asahi Roentgen Ind. Co., Ltd., Kyoto) is widely used to obtain intraoperative X-ray images for electrode position verification. Deep brain stimulation (DBS) surgeries require accurate stereotaxy for a successful outcome. After modifying the procedure according to Japanese specifications, the accuracy of neuromate localization was examined on a computed tomography (CT) phantom preparation.

Robotic surgery systems, such as the Da Vinci device, require substantial training, and all surgeons must complete the training curriculum. Moreover, when first using the robot, the procedure should be carefully monitored under the direction of an independent department at the surgeons' institute. At our hospital, operative guidelines were recently completed, as directed by the Risk Management Office and Advanced Medical Committee. These guidelines include a training system for surgeons and operative nurses. Surgical staffs follow the operative guidelines and prepare for clinical application of the neuromate system using stereotactic DBS.

The neuromate robot can be applied either with a stereotactic base frame or in frameless mode utilizing ultrasound registration. Regarding the application accuracy, frame-based procedures are more accurate than frameless procedures.[5] We initiated the first frame-based neuromate surgery application with DBS surgery, with frameless neuromate robot procedures introduced in a subsequent step.

Methods

1. Modification of the neuromate robot for Japanese specifications

a. Stereotactic X-ray system

It is necessary to confirm that the recording electrode is placed in the planned position. The mobile stereotactic X-ray system manufactured by Asahi Roentgen Ind. Co. Ltd., is widely used among institutes in which stereotactic surgery is performed in Japan. This system consists of an X-ray camera with a joint arm to be installed on a mounting plate designed for the Leksell® G frame and positioned to be always parallel to the X or Y axis of the frame and X-ray film cassette. The mobile stereotactic X-ray system is conventionally installed with the mounting plate calked with two metal bars at the end of the operating table. We installed the X-ray system by attaching the mounting plate to a newly developed adapting plate which was securely bolted to the adaptor base at one end of the extension plate toward the neuromate body in a triangle shape on the base where the patient's head was normally fixed in order to intraoperatively obtain both anteroposterior and lateral images (Fig. 2). The adjustable X-ray camera at the end of the arm rotates for image acquisition in two directions. However, we realized that the weight of the X-ray camera and its arm installed at one end of the mounting plate was heavy enough to cause slight skewness in the adaptation, thereby affecting the targeting accuracy of the system. This issue was resolved by introducing calibration

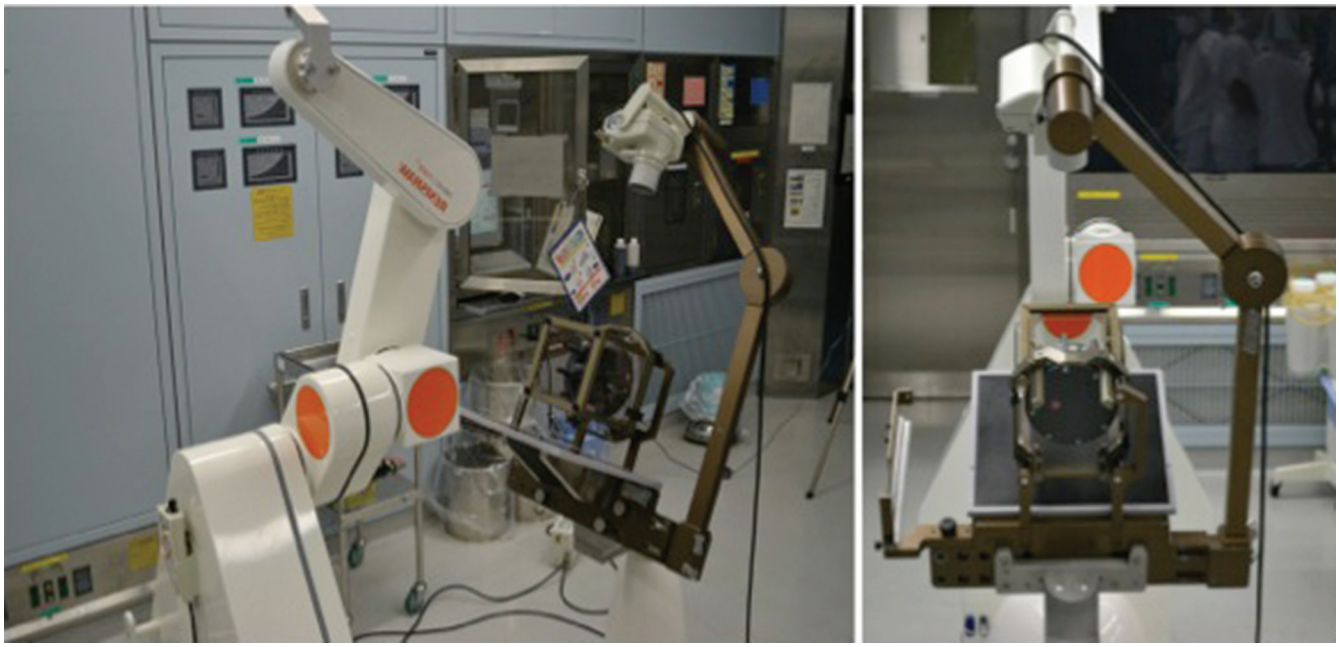

Fig. 2 The stereotactic X-ray system was mounted to the base of the neuromate at the location of the patient's head position using a bolted structure.

employing the stereotactic X-ray system installed to address the problem during the calibration process. In this way, stereotactic accuracy was successfully maintained despite the weight of the X-ray camera and its arm, which rotated repeatedly. The original X-ray film table was found to be too long to potentially interfere with the movement of the neuromate robot arm and, therefore, X-ray film cassettes of smaller size were used with attention during robot arm movement. It is highly recommended that the X-ray film table be modified to be detachable.

Stereotactic accuracy was examined following neuromate system calibration using the stereotactic X-ray system to verify the impact of the modification.

b. Operating table

It is preferable that the patient's head could be placed upward to prevent cerebrospinal fluid (CSF) leakage during the procedure. However, the neuromate robot was designed to be used in a flat position. In our hospital, the patient's head is supported with a frame using the X-ray system mounting plate fixed with a 25-degree angle onto the extension plate on the robot's static base, with the adaptation described above. In this way, we modified the patient's head position for use with the neuromate to accommodate a tilted operating table holding the patient's upper body adequately close to the robot system. The adaptor plate and base with a 25-degree angle were developed for the robot base to accommodate the position of the patient's head and the back of the operating table, which was tilted by 25 degrees (Fig. 3). Stereotactic localization was performed in the configuration of the angled head position using the system recognizing tilted frame coordinates to achieve the same level of stereotactic accuracy as the standard neuromate set-up.

c. Microelectrode recording

Electrophysiological recording allows the surgeon to determine the optimum location for stimulation, while minimizing side effects. Successful microelectrode recording requires that the operative environment be shielded from electrical noise. Our microelectrode recording instruments include an amplifier (Lead point; Medtronic Co., Ltd., Minneapolis, USA), oscilloscope (4 ch, > 20 MHz, TDS 420A, Tektronix Co., Ltd., Oregon, USA), audio monitor and speaker (Onkyo Co. Ltd., Osaka) with a storage system for data recording [16-ch data recorder (20k Hz X1, 5kHz ×8, > 6 hrs, Sony Co. Ltd., Tokyo) Hum Bug (Quest Scientific Co. Ltd., USA], and a computer to analyze the data (Toshiba Co. Ltd., Tokyo). The neuromate robot itself tends to produce some electric noise. The effect of such electrical noise on our microelectrode recording setup was examined using a 1 KΩ electrical resistor. The 1 KΩ electrical resistor was placed close to the arm assembly and body of the neuromate robot, resulting in the absence

Fig. 3 The base of the patient's head position was tilted by 25 degrees to obtain an easy configuration by raising the back of the operating table.

of electrical noise interference on the oscilloscope audio monitor and speaker. The neuromate did not appear to interfere with the microelectrode recording.

2. Guidelines and training

The operative guidelines were completed as directed by the Risk Management Office and Advanced Medical Committee at our hospital. The guidelines stated that the training course should include a basic lecture class, hands-on training, and on-site training (skill evaluation and approval by expert neurosurgeons in Europe). We held a lecture for surgeons and operative nurses to explain the operation of the device and associated mechanisms and emergency measures on September 25, 2011. There was a small test to assess the participants' level of understanding. We subsequently offered hands-on training for the neuromate procedure. The author (Kajita Y.) received on-site training provided by two expert neurosurgeons, Prof. Emanuel Cuny at University Hospital de Bordeaux, France and Prof. Philippe Decq at University Hospital Henri Mondor, France in November 2011. The skills of the author in performing the robot procedure were evaluated and validated by these individuals (Table 1). The ethics committee of our hospital approved our clinical research on neuromate robot surgery for use in patients with Parkinson's disease (PD) in December 2011.

Results

Application accuracy of the neuromate

a. Neuromate calibration

The calibration of the intrinsic robot arm accuracy is performed with the goal of achieving an

Table 1 Renishaw neurosurgical robot neuromata

Operation Skill Evaluation Sheet

1. **DBS surgical planning**
   a. properly identify a stereotactic surgery target anatomically and functionally.
   b. define an appropriate electrode insertion trajectory.
   c. define safety volume around the patient's head to prevent collisions by a robot arm or a tool holder.
2. **Neuro l mate system set-up**
   a. position neuro l mate properly to the patient's head.
   b. set-up operation braking system properly.
   c. fix stereotactic frame to a patient's head properly.
   d. adapt Elekta X-ray system to neuro l mate (not applicable to on-site training).
3. **Basic robot operation and emergency operation**
   a. select appropriate operation mode.
   b. select appropriate robot arm configuration.
   c. remove robot arm from the patient's head under emergency situation.
4. **Tool holder installation**
   a. install a laser tool holder to the robot arm.
   b. install surgery tools to a standard tool holder according to applications.
5. **Surgery tool operation**
   a. operate electrode introducing guide, micro recording electrode, and stimulation electrode properly.
6. **System close-down operation**
   a. remove the robot arm to a parking position.
   b. release the patient's head with a stereotactic frame from neuro l mate system.
7. **Evaluation results**

Evaluation points	Result (Y / N)
1. DBS surgical planning	
2. Neuro l mate system set-up	
3. Basic robot operation and emergency operation	
4. Tool holder installation	
5. Surgery tool operation	
6. System close-down operation	

Date of evaluation:
Site:
Evaluator:
Trainee:

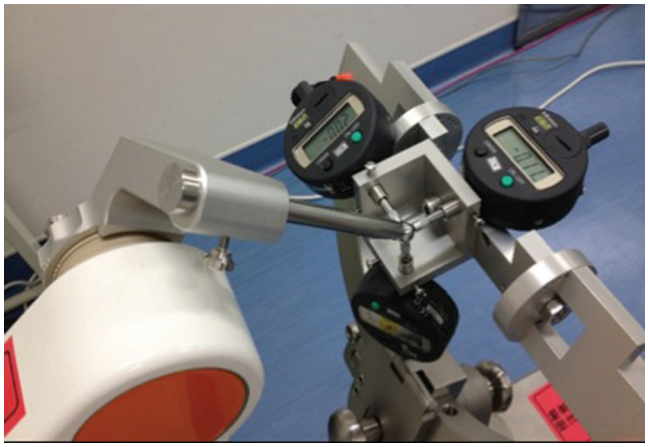

Fig. 4 The intrinsic accuracy of the arm is defined as the minimal radius of a sphere centered on the actual target.

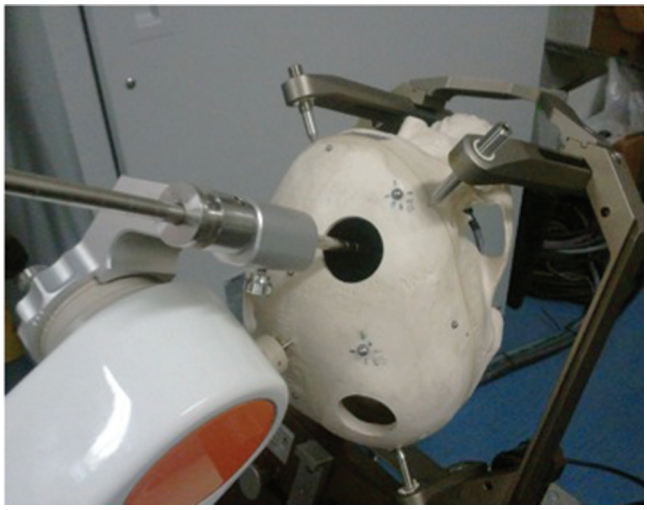

Fig. 5 The phantom was fitted with implantable markers. The markers were used to accurately measure the location of the probe tips placed according to each of the frame-based methods.

accurate target at the prescribed point in multiple arm configurations and surgical tool orientations that best suits the surgical environment, such as factors related to surgical laterality and the corresponding surgeon's position, medical equipment set-up, and so on. This process begins by defining three-dimensional (3D) coordinates of one point as the position, then targeting the zero position based on 19 arm configurations, including symmetric configurations, in order to measure the differences between the zero position and actual target points in three axes for the purpose of obtaining the distribution of the targeting errors (Fig. 4). Referring to the distribution, parameters for arm control are adjusted accordingly using the system control software program. System maintenance with the calibration plate was regularly conducted every 3 months for the above-mentioned reasons, and the accuracy at installation was maintained.

b. CT phantom accuracy

Leksell G frame-based stereotactic surgery was applied as our routine DBS procedure. The application accuracy of the neuromate robot was examined using Leksell G frame-based stereotaxy (Fig. 5). In this study, CT was chosen because there were no errors of imaging distortion in such images. The phantom was imaged using a CT scanner (Aquilion64™, Toshiba Medical Systems Co. Ltd, Tokyo). Scan thickness was set at 0.5 mm, and the image resolution used was of pixel size 0.5 mm × 0.5 mm. The acquired images are entered into the planning software program to define at least five trajectories to different targets. The root mean square (RMS) was calculated to show the differences between the actual points and the measured points. A systematic error analysis was performed by comparing the coordinates of target points on the medical images with those of digitized target points. Statistical analysis was performed on the experimental data. A comparison of the 3D measurements (X, Y, Z) of the coordinates of the six target points (Vox 1–Vox 6) from each experimental data point obtained with the fiducial markers to the absolute image coordinates was performed. The mean deviation from the absolute image coordinates was calculated from all 3D mean measurements (X, Y, Z).

The mean ± standard deviation (SD) error of the 3D X, Y, and Z axis measurements (minimum–maximum value) was 0.05 ± 0.05 mm for X (0.00–0.20), 0.06 ± 0.07 mm for Y (0.00–0.20), and 0.06 ± 0.07 mm for Z (0.00–0.20). The mean root mean square (RMS) was 0.12 ± 0.10 mm (minimum: 0.00 mm – maximum: 0.28 mm) (Table 2).

Discussion

The neuromate robot includes a five degree-of-freedom robotic arm assembly and PC-based kinematic positioning software system. The surgeon is able to precisely plan the trajectory and accurately and flexibly maneuver the fitted articulated surgical tools.

Compared with the conventional manual stereotactic system, neuromate has some advantages including less human error or easier multiple procedures

Table 2 Errors of three-dimensional measurements

	Vox_1	Vox_2	Vox_3	Vox_4	Vox_5	Vox_6	Mean
Ex	0	0.1	0.1	0	0.1	0	0.05
Ey	0	0.1	0.1	0	0	0.2	0.06
Ez	0	0	0.1	0	0.1	−0.2	0.06
E Total	0	0.14	0.17	0	0.14	0.28	0.12

Ex: error of X axis, Ey: error of Y axis (mm), Ez: error of Z axis (mm), E Total: root mean square (mm).

Table 3 Comparison between manual stereotactic and neuromate methods

	Manual	Neuromate
Human error	Yes	Less
Mechanical error	Increases as used	Maintained by service
System accuracy	Decreases as used	Maintained by service
Multiple procedure facilitation	Troublesome	Easy
Frameless mode	No	Yes
Cost	Low	High

facilitation. Table 3 summarizes the comparison between manual stereotactic surgery and neuromate method (Table 3).

In neuromate procedures, the patient's head is supported on the robot base, while a tool holder on the robot arm functions as a solid base for holding and manipulating the surgical tools. The robot provides fine adjustment and precise control. The use of the neuromate robot reduces the degree of error by precisely positioning the surgical tools to preprogrammed coordinates, with a high degree of accuracy and reproducibility.

The neuromate robot has been continuously developed since it was previously introduced in Japan in 1995.[5] The robot arm approaches the prescribed target position with multiple arm configurations. The operative algorithm of the five degree-of-freedom robotic arm assembly has become more sophisticated, now reaching the target more linearly compared with previous versions. The motion speed of the robot arm is set at two stages. The robot arm operates at a standard speed (100 mm/sec and 0.075 rad/sec) outside a defined area around the patient's head and at a reduced speed (two-thirds of the standard speed) in the safety area between the predefined and user-defined software safety volume where the robot arm does not enter. The most recent neuromate robot is designed to be compact, with three casters for mobility. Hence, it is kept out of the operating room and brought in on the day of surgery.

Neuromate robots are regularly used in stereotactic procedures such as DBS, biopsies, and stereo electroencephalography (SEEG), as well as neuroendoscopic approaches worldwide, especially in Europe.[6–10] In DBS surgeries, it is necessary to confirm that a recording electrode is placed in the planned position. In Europe, two X-ray sources are installed in the walls and ceiling in the operating room at a distance of 3.5 m to 5 m to the patient.[11] In contrast, the mobile stereotactic X-ray system attached to an operating table is widely used in Japan. In frame-based neuromate DBS surgeries, the stereotactic X-ray system holding the stereotactic frame is mounted on the robot base with firm adaptation and a twist in the calibration procedure to prevent any impact on system accuracy. In addition, a smaller X-ray film cassette is employed to avoid interference with the operation of the robot arm.

The neuromate is designed for use with the patient in the supine position on a flat operating table. However, it is preferable that patient be placed with their head positioned upward to prevent CSF leakage during the procedure. The patient's head is supported in the frame on the stereotactic X-ray system mounted to the robot's static base. Therefore, the robot base on which the patient's head is to be fixed is tilted by 25 degrees to accommodate the back of the operating table in a tilted position.

In this study, the mean error of the 3D mean measurements was 0.05 mm for the X axis, 0.06 mm for the Y axis, and 0.06 mm for the Z axis. The mean RMS was 0.12 mm. In contrast, in our 19 DBS surgeries among patients with PD performed using 1.5T magnetic resonance imaging (MRI) and Leksell G frame-based procedures, the mean ± SD error (minimum–maximum value) of the 3D measurements was 0.74 ± 0.53 mm for the X axis (0.2–2.5 mm), 0.70 ± 0.78 mm for the Y axis (0.0–4.0 mm), 0.40 ± 0.07 mm for the Z axis (0.0–2.0 mm), and the mean ± SD RMS was 1.36 ± 0.83 mm. Fukaya et al. reported that the deviation in frame-based surgery in 20 patients (40 electrodes) was 1.5 ± 0.9 mm (mean ± SD) in the mediolateral (X), 1.1 ± 0.7 mm in the anteroposterior (Y), and 0.8 ± 0.6 mm in the superoposterior (Z) directions.[12] The accuracy of clinical application of this device differs from the factory calibration (mechanical accuracy) in that it includes compounded errors when used in the clinical setting. Such errors include image errors, digitization errors, registration errors, and computation errors.

Neuromate robots can be used with either a stereotactic frame or in a frameless mode. Li et al. demonstrated that, with respect to application accuracy, frame-based procedures are superior to frameless procedures.[5] However, Varma et al. reported that, in a phantom study, the application accuracy was 1.29 mm[13]; the neuromate robot was subsequently used in 153 functional neurosurgical procedures, including 113 DBS lead implantations. The authors concluded that the neuromate stereotactic robot, when applied in the frameless mode, demonstrated sufficient accuracy for a range of functional neurosurgical procedures. Therefore, the neuromate may be used for functional neurosurgery with a frameless ultrasound registration system as the next step in Japan.[14]

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Conflicts of Interest Disclosure

All authors have no conflict of interest.

References

1) Xia T, Baird C, Jallo G, Hayes K, Nakajima N, Hata N, Kazanzides P: An integrated system for planning, navigation and robotic assistance for skull base surgery. *Int J Med Robot* 4: 321–330, 2008
2) Zamorano L, Li Q, Jain S, Kau G: Robotics in neurosurgery: state of the art and future technological challenges. *Int J Med Robot* 1: 7–22, 2004
3) Sayama Y, Nakagawara J, Sasaki M, Takeda T, Nakamura H: Neuo Mate ni yoru Robotized Stereotaxy. *Sentan Iryou* 5: 79–81, 1998
4) Ohye C, Fodstad H: Forty years with Professor Narabayashi. *Neurosurgery* 55: 222–226; discussion 226–227, 2004
5) Li QH, Zamorano L, Pandya A, Perez R, Gong J, Diaz F: The application accuracy of the NeuroMate robot—a quantitative comparison with frameless and frame-based surgical localization systems. *Comput Aid Surg* 7: 90–98, 2002
6) Dellaretti M, Reis BL, Touzet G, Reyns N, Dubois F, Gusmao S, Serge B: Brainstem biopsies in adults: review of 80 consecutive cases. *Arq Bras Neurocir* 28: 139–142, 2009
7) Haegelen C, Touzet G, Reyns N, Maurage CA, Ayachi M, Blond S: Stereotactic robot-guided biopsies of brain stem lesions: experience with 15 cases. *Neurochirurgie* 56: 363–367, 2010
8) Gallina P, Paganini M, Di Rita A, Lombardini L, Moretti M, Vannelli GB, Di Lorenzo N: Human fetal striatal transplantation in huntington's disease: a refinement of the stereotactic procedure. *Stereotact Funct Neurosurg* 86: 308–313, 2008
9) Gallina P, Paganini M, Lombardini L, Mascalchi M, Porfirio B, Gadda D, Marini M, Pinzani P, Salvianti F, Crescioli C, Bucciantini S, Mechi C, Sarchielli E, Romoli AM, Bertini E, Urbani S, Bartolozzi B, De Cristofaro MT, Piacentini S, Saccardi R, Pupi A, Vannelli GB, Di Lorenzo N: Human striatal neuroblasts develop and build a striatal-like structure into the brain of Huntington's disease patients after transplantation. *Exp Neurol* 222: 30–41, 2010
10) Derrey S, Blond S, Reyns N, Touzet G, Carpentier P, Gauthier H, Dhellemmes P: Management of cystic craniopharyngiomas with stereotactic endocavitary irradiation using colloidal 186Re: a retrospective study of 48 consecutive patients. *Neurosurgery* 63: 1045–1053; discussion 1052–1053, 2008
11) Benabid AL, Chabardès S, Seigneuret E, Hoffmann D, Le Bas JF: *The Talairach Stereotactic System*: *Textbook of Stereotactic and Functional Neurosurgery.* New York, Springer Publishing Company, 2009
12) Fukaya C, Sumi K, Otaka T, Obuchi T, Kano T, Kobayashi K, Oshima H, Yamamoto T, Katayama Y: Nexframe frameless stereotaxy with multitract microrecording: accuracy evaluated by frame-based stereotactic X-ray. *Stereotact Funct Neurosurg* 88: 163–168, 2010
13) Varma TR, Eldridge P: Use of the NeuroMate stereotactic robot in a frameless mode for functional neurosurgery. *Int J Med Robot* 2: 107–113, 2006

14) Rossi A, Trevisani A, Zanotto V: A telerobotic haptic system for minimally invasive stereotactic neurosurgery. *Int J Medi Robot* 1: 64–75, 2005
15) Cossu M, Cardinale F, Castana L, Citterio A, Francione S, Tassi L, Benabid AL, Lo Russo G: Stereoelectroencephalography on the presurgical evaluation of focal epilepsy: a retrospective analysis of 215 procedures. *Neurosurgery* 57: 706–718; discussion 706–718, 2005
16) Afif A, Chabardes T, Minotti L, Kahane P, Hoffmann D: Safety and usefulness of insular depth electrodes implanted via an oblique approach in patients with epilepsy. *Neurosurgery* 62(5 Suppl 2): ONS471–ONS479; discussion 479–480, 2008
17) Procaccini E, Dorfmüller G, Fohlen M, Bulteau C, Delalande O: Surgical management of hypothalamic hamartomas with epilepsy: the stereoendoscopic approach. *Neurosurgery* 59(4 Suppl 2): ONS336–ONS344; discussion ONS344–ONS346, 2006

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