A robotic device for performing intracranial procedures, comprising a baseplate for mounting on the subject's skull and a rotatable base element rotating on the baseplate. The rotatable base element has a central opening through which a cannulated needle can protrude such that it can rotate around an axis perpendicular to the baseplate. This cannulated needle is robotically controlled to provide motion into and out of the subject's skull. A flexible needle is disposed coaxially within the cannulated needle, and it is controlled to move into and out of a non-apical aperture in the distal part of the cannulated needle. Coordinated control of the insertion motion of the cannulated and flexible needles, and rotation of the combined cannulated/flexible needle assembly enables access to be obtained to a volume of a region of the brain having lateral dimensions substantially larger than the width of the cannulated needle.
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ROBOT FOR MINIMALLY INVASIVE NEUROSURGERY

FIELD OF THE INVENTION

The present invention relates to the field of robotic systems for use in minimally invasive surgical and diagnostic procedures, especially for use in performing cranial neurosurgery.

BACKGROUND OF THE INVENTION

As of today, brain surgeries remain complex and risky. Conventional open skull surgery is traumatic, may have debilitating side effects to the patient and generally requires long recovery time. The time taken to perform the surgery may be tedious and decreases the efficiency of the medical staff. The complexity of the operations often prevents repeatability if required. The operation itself may cause a brain-shift, and for operations such as tumor resection, the original position of the tumor may be dislocated so that pre-operative planning may no longer be accurate interoperatively.

Therefore exists a need for a minimally-invasive and automated procedure, which overcomes at least some of the disadvantages of prior art procedures.

The disclosures of each of the publications mentioned in this specification, are hereby incorporated by reference, each in its entirety.

SUMMARY OF THE INVENTION

The present disclosure describes new exemplary automated robot-based platforms for minimally-invasive neurosurgical use, including procedures such as resection of brain tumors or the extraction of multiple biopsy samples from large volumes of the brain, or others. Unlike other existing robotic approaches that mimic the surgeon's hand motion, and which therefore generally require substantive access to the operation region, the presently described technology uses the unique capabilities of robotic systems for minimally invasive access to
regions of the brain with minimal collateral tissue damage, on the basis of predetermined motion of the robotic actuator holding the surgical tool, which is accurately positioned and moved by the robotic control. The region of the brain to be treated is first mapped using an imaging modality such as CT, MRI or Ultrasound. Based on these images, the surgeon decides on the best path to reach the tumor, if that is the target of the procedure, with minimal trauma to surrounding brain tissue.

Some prior art robotic systems for neurosurgery, such as the NeuroMate supplied by Renishaw pic of Wotton-under-Edge, Gloucestershire, U.K., access the brain along one trajectory line and can make a procedure such as a biopsy, or a DBS only along that line. The present invention enables access to a larger volume through a single entrance passage. As a result, less brain tissue is damaged during the access process. A small key-hole incision is made in the skull, and a narrow path is traced by the robotic tool to reach the desired location. The robot advantageously consists of a rigid cannulated needle with a distally positioned laterally directed hole. A flexible needle is advanced through the bore of the cannulated needle, and delivered to the diseased area through the distal hole. The motion of the two needles are computer controlled such that every point in the vicinity of the distal end of the needle can be reached by controlling the insertion depth and the orientation of the rigid needle, and the relative insertion depth of the flexible needle. Using such an arrangement an insertion path width of less than 5mm is possible. When the desired location is reached, the surgical tool at the end of the flexible needle can be actuated to treat the accessible volume of the tumor. The flexible needle is constructed such that it can perform physical cutting operations, or can deliver an electric current, ablative or phototherapeutic heat or light, or ultrasound energy to treat, for instance, a tumor. For drug delivery the internal flexible needle can be cannulated. For biopsies the needle may be constructed to extract tissue samples. By this means, multiple samples over a large volume to be inspected, can be taken using only one small incision. Access to regions of the brain beyond the operational access of the flexible needle end in a single extension can be reached by withdrawing the flexible needle to within the rigid cannulated needle, and then withdrawing the rigid cannulated needle somewhat, or inserting it further, in order to reposition it to provide access by the inner flexible needle to the new region to be accessed, whether into a deeper or a
less deep region of the brain, and at whatever azimuthal angle is needed relative to the first treatment performed.

The needle motion can be controlled in two modes:
1. Based on preoperative planning, whereby the shape and position of the diseased area is known from preoperative images, and hence the motion needed to reach specific points within the diseased area is known. This mode will require a registration procedure to be performed, generally using markers having known positions and visible in the preoperative images, in order to relate the robotic coordinate system to the co-ordinate system of the images. Alternatively, registration can be achieved by surface matching techniques, whereby an intra-operative scan of the subject's head, including at least some anatomic features such as the subject's facial features, and some known features of the mounted robot, is compared with a preoperative scan of the subject's head. Matching of the anatomical features then enables the position of the robot to be determined relative to the preoperative images.
2. Real time control using an external or internal imaging system, such as MRI, CT, ultrasound, or needle mounted sensors. The latter option may use optical, electrical or ultrasound sensors, mounted on either or both the flexible needle and the external rigid needle. Such needle mounted sensors can then be used to detect not only the position of the needle tip, but also to provide data regarding the physiological state and condition of the surrounding tissue.

As an alternative to use of the base element fixed directly to the skull, it is possible to use any of the conventional mounting hardware such as a stereotactic frame in order to attach the needle assembly in a predetermined position to the patient's skull. In such a case, prior art methods can be used to determine the direction of penetration of the treatment needle. In such prior art methods, the region to be treated is defined on preoperative images, which include the mounting hardware used to support the needle insertion device, and the position of the device relative to the mounting hardware is known, such that the device is registered to the preoperative images. The surgeon then defines the orientation angles and depth of penetration of the needle, using the alignment facilities provided on the mounting hardware. Using prior art methods of a single needle inserted straight into the patient's brain, there may be situations where access to the target point is problematic because of sensitive or damage prone regions of
the brain in the direct linear access path. Use of the present device enables access to be achieved along a singly articulated path without encountering the sensitive or damage-prone regions of the brain.

Additionally, if adjustable mounting hardware is used, it is possible to access in two dimensions, locations which would otherwise be problematic to reach by a direct linear path. The specific target area is reached by first aligning the device using the mounting frame adjustments, and then a controlled sequential combination of (i) the depth of entry of the cannulated needle and then (ii) the extension of the flexible needle, to reach the target area.

The surgeon can at any time, take active control of the robot and change the operation plan if necessary.

The small access path minimizes brain shift during the surgery and improves operation accuracy and reduces morbidity. This technology allows the robot to reach more areas in the brain from a single cranial incision than previously possible, and opens new horizons in treating brain tumors.

There is thus provided in accordance with an exemplary implementation of the devices described in this disclosure, a robotic device for performing intracranial procedures, comprising:
(i) a baseplate adapted for mounting on the skull of a subject,
(ii) a rotatable element disposed on the baseplate, and having an opening in its central region,
(iii) a first, cannulated needle mounted on the rotatable element coaxially with the opening, and which rotates with rotation of the rotatable element, the first cannulated needle being robotically controlled to provide motion into and out of the skull of the subject, and
(iv) a second, flexible needle disposed in the first cannulated needle, the second flexible needle being controlled to provide motion into and out of a non-axial aperture in the distal part of the first cannulated needle,

wherein coordinated control of the insertion motion of the first and second needles and rotation of the rotatable element enables access to be obtained by the second flexible needle to a target region of the brain where the procedure is to be performed.

In such a device, the target region accessed by the device may have lateral dimensions substantially larger than the width of the first cannulated needle. The
device may also be adapted to provide the access to the target region of the brain
with collateral trauma to non-accessed parts of the brain being approximately
confined to a region having the width of the first cannulated needle, and the target
region of the brain may be located in a region of the brain where a direct access
path from an external insertion point would pass through a region of the brain
subject to damage by the flexible needle.

Accordingly, such a device may use coordinated control of the insertion
motion of the cannulated and flexible needles and rotation of the rotatable
element to enable access to be obtained by the flexible needle to the target region
of the brain along an articulated path selected to avoid damage-prone regions of
the brain.

In any of these devices, the second flexible needle may comprise a cutting
tool, such that resection of a brain tumor can be performed with collateral trauma
to those parts of the brain not being treated being approximately confined to a
region having the width of the first cannulated needle. Additionally, the second
flexible needle may be adapted to be connected to an energy delivery system,
such that ablation or electro-treatment of a brain tumor can be performed with
collateral trauma to those parts of the brain not being treated being approximately
confined to a region having the width of the first cannulated needle. The energy
may be any one of thermal, electrical, optical or ultrasound energy. If thermal or
optical energy, the device may comprise an optical fiber disposed within the
second flexible needle for delivery of the thermal or optical energy, or the second
flexible needle may itself be an optical fiber for delivery of the thermal or optical
energy.

In such devices, the second flexible needle may comprise a biopsy tool,
such that biopsy samples may be obtained from regions of the brain at different
positions laterally displaced from each other by distances substantially larger than
the width of the first cannulated needle, with collateral trauma to those parts of the
brain not being accessed being approximately confined to a region having the
width of the first cannulated needle. Alternatively, the second flexible needle may
comprise a drug delivery passage, such that a drug can be delivered to regions of
the brain at different positions lateral displaced from each other by distances
substantially larger than the width of the first cannulated needle, with collateral
trauma to those parts of the brain not being accessed being approximately confined to a region having the width of the first cannulated needle.

Additionally, in any such devices, the non-axial aperture in the distal part of the first cannulated needle may be a hole in the wall of the first cannulated needle, or it may be an opening having a robotically directed variable angle exit aperture at the end of the first cannulated needle.

Furthermore, any of the above described robotic devices, may further comprise a set of preoperatively inserted markers for relating the position of the robotic device to the skull of a subject, such that the co-ordinate system of the robotic device can be registered to a preoperative image of the skull of the subject. Alternatively, they may comprise at least one position sensor disposed in the distal region of the second flexible needle, such that the real time position of the second flexible needle tip can be monitored intraoperatively, or at least one position sensor disposed in the distal region of the first, cannulated needle, such that the real time position of the first cannulated needle tip can be monitored intraoperatively.

Systems using the above described robotic devices may further comprise an imaging system, such that the real time position of at least one of the first cannulated needle tip, and the second flexible needle tip can be monitored intraoperatively.

Additionally, such robotic devices may further incorporate a sensor capable of detecting the boundaries between healthy and tumor tissues, and wherein such robotic device is adapted to use information regarding the boundaries to control the motion of the flexible needle.

Another example implementation can involve a robotic device for performing neurosurgical procedures at a target region of the brain, comprising:

(i) a baseplate adapted for attaching in a predetermined orientation and position on the skull of a subject,
(ii) a cannulated needle mounted on the baseplate, the cannulated needle having a non-axial aperture in its distal part, and a motion controller to provide motion into and out of the skull of the subject, and
(iii) a flexible needle disposed in the cannulated needle, the second flexible needle having a motion controller to provide motion into and out of the non-axial aperture in the distal part of the cannulated needle,
wherein coordinated control of the insertion motion of the cannulated and flexible needles enables access to be obtained by the flexible needle to the target region of the brain along an articulated path selected to avoid damage-prone regions of the brain.

In such a robotic device, the target region accessed by the device may have lateral dimensions substantially larger than the width of the first cannulated needle. The device may also be adapted to provide the access to the target region of the brain with collateral trauma to non-accessed parts of the brain being approximately confined to a region having the width of the first cannulated needle, and the target region of the brain may be located in a region of the brain where a direct access path from an external insertion point would pass through a region of the brain subject to damage by the flexible needle.

Accordingly, such a device may use adjustment of the predetermined orientation and position of the baseplate on the skull of a subject and coordinated control of the insertion motion of said cannulated and flexible needles to enable access to be obtained by the flexible needle to the target region of the brain along an articulated path selected to avoid damage-prone regions of the brain.

In such a robotic device the second flexible needle may comprise a cutting tool, such that resection of a brain tumor can be performed, with collateral trauma to those parts of the brain not being treated being approximately confined to a region having the width of said first cannulated needle.

Yet other implementations perform a method of performing intracranial procedures, comprising:

(i) providing a baseplate and mounting it on the skull of a subject, the baseplate having disposed on it a rotatable element with an opening in its central region,

(ii) mounting on the rotatable element, coaxially with the opening, an assembly comprising:

(a) a first, cannulated needle which rotates with rotation of the rotatable element, the first cannulated needle being robotically controlled to provide motion into and out of the skull of the subject, and

(b) a second, flexible needle disposed in the first cannulated needle, the second flexible needle being controlled to provide motion into and out of a non-axial aperture in the distal part of the first cannulated needle,
(iii) coordinating the rotation of the rotatable element and the sequential insertion of the first and second needles to enable access to be obtained by the second flexible needle to a target region of the brain where the procedure is to be performed.

Yet a further implementation may involve a method of performing neurosurgical procedures at a target region of the brain, comprising: (i) attaching in a predetermined orientation and position on the skull of a subject, a base element, (ii) mounting on the base element, an assembly comprising: (a) a cannulated needle, the cannulated needle having a non-axial aperture in its distal part, and a motion controller to provide motion into and out of the skull of the subject, and (b) a flexible needle disposed in the cannulated needle, the second flexible needle having a motion controller to provide motion into and out of the non-axial aperture in the distal part of the cannulated needle, (iii) selecting on a preoperative image of the brain, a singly articulated path avoiding damage-prone regions of the brain, and (iv) controlling the sequential insertion motion of the cannulated needle and the flexible needle to enable access to be obtained by the flexible needle to the target region of the brain along the singly articulated path.

It is to be understood that the term needle, as used and as claimed in the present application is intended to apply to the element inserted through the bore of the external rigid cannula, whether that element is a full needle, such as for delivering a biopsy harvesting tool, or a sensor or an electrode, or the like, or whether that needle is hollow, such as for drug delivery, or for extracting a fluid sample, or the like.

BRIEF DESCRIPTION OF THE DRAWINGS

The presently claimed invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:
Figs. 1A and 1B illustrate schematically an exemplary implementation of a robotically controlled neurosurgical apparatus using a double cannulated needle assembly, as described in this disclosure;

Fig. 2 illustrates schematically how the complete double needle assembly of Fig. 1A can be advanced through the holes in the base sections of the device, using a motor-encoder assembly;

Fig. 3 illustrates schematically how the internal flexible needle of the assembly of Fig. 2 can be advanced outside of the external rigid needle, so that its tip can reach the regions of the brain which it is desired to treat;

Figs. 4A and 4B illustrate alternative methods to that of Fig. 3, of enabling the tip of the internal needle to reach any part of the region to be treated;

Fig. 5 illustrates schematically a complete practical robotic system based on the systems shown in the above Figures; and

Fig. 6 illustrates schematically further exemplary implementations of needle insertion devices using conventional head clamping devices.

DETAILED DESCRIPTION

Reference is now made to Figs. 1A and 1B, which illustrate schematically an exemplary implementation of a robotically controlled neurosurgical apparatus according to the novel designs presented in this disclosure. A central feature of this neurosurgical robot implementation is a combination of a flexible needle 4 which can be controllably inserted into an external rigid cannular needle 3. Although the flexible needle is shown in the drawings of this disclosure as a solid needle, it can, as previously mentioned, be either solid or cannulated. The shape of the external rigid needle is shown in Fig. 1B. At its distal tip 21, the bore of the external needle is diverted laterally, so that the distal opening is directed sideways from the bore of the needle, at an angle to the axis of the bore of the needle. In Figs. 1A and 1B, the exit angle is shown as approximately 45° to the cannula axis, though it is to be understood that this angle can be selected to enable ease of passage of the flexible needle around the bend of the bore, depending on the flexibility and diameter of the flexible needle 4. The external needle should advantageously be made of a rigid metal, which should not be a ferromagnetic metal if an MRI system is to be used for the intraoperative real-time imaging. The
internal needle may be made of a flexible metal such as Nitinol, or, if the stresses to be applied to it are not excessive, of a plastic material, the level of flexibility being such that it can negotiate the bend at the tip of the external needle while maintaining its shape after leaving the lateral hole of the external needle.

As shown in the exemplary robot of Fig. 1A, the combination of internal and external needles are mounted above an opening in a base section 2, which itself is rotatably mounted on a main base 1. Rotation of the base section 2 around the main base 1 may be performed by means of a robotic actuation motor 5, which should also include an angular position encoder, so that the angular orientation of the base section 2 is known. Correct rotation of the base section 2 relative to the opening in the base section should be ensured, such as by means of a circular slide and guide arrangement, as shown on the top surface of the main base 1. It is also important that the external cannula 3 and its contents rotates in exact unison with the base, since otherwise, the base encoder would give incorrect readings for the angular position of the needle assembly. This can be achieved either by ensuring that the rotary friction of the external needle with the rotating base is much higher than the expected friction force between the brain tissue and the needle after insertion, or by provision of a mechanism to positively fix the angular position of the needle assembly to the base, such as a key-way running down the length of the outer wall of the cannulated needle such that it can slide relative to the rotating base, but cannot rotate independently thereof.

The insertion of the internal flexible needle within the external needle may be controlled by means of a robotic motor and encoder 7, as shown in Fig. 1A, or by means of a linear motor (not shown). If a rotary drive is used, access to the flexible needle 4 can be obtained by means of a slot in the external cannula wall. Alternatively, the inner flexible needle 4 can be moved from its proximal end section protruding from the external cannula 3. The linear insertion and extraction motion of the complete double needle assembly relative to the base plate may be controlled by means of another motor and encoder 6. If the system is to be used with MRI intraoperative imaging, linear or rotary piezoelectric motors may advantageously be used to provide the motion.

Reference is now made to Fig. 2, which illustrates schematically how the complete double needle assembly 3, 4, can be advanced through the holes in the
base sections, using the motor-encoder assembly 6, until the distal tip of the assembly has accessed the region 22 of the brain which it is desired to treat.

Reference is now made to Fig. 3, which illustrates schematically how, once the combined needle assembly 3-4 has been rotated so that the distal opening 21 in the cannulated needle is orientated within the region 22 of the brain to the first part to be treated, the internal flexible needle 4 can be advanced outside of the external rigid needle 3, using the motor-encoder 7, so that the tip of the internal flexible needle can reach that part of the regions the brain which it is desired to treat. Since in the implementation shown in Figs. 1 to 3, the exit angle of the internal needle is fixed, the combined motion of all three motors is necessary in order to provide access to any part of the entire volume of the region to be treated. Thus, combined activation of the motor 6 to drive the depth of penetration of the external needle 3, and the motor 7 to drive the extent of the lateral extension of the internal needle 4 from the exit of the external needle, enables the full two-dimensional area shown in the drawings to be accessed. The vertical arrow marked V indicates the motion direction enabled by insertion and withdrawal of the external annular needle 3, and the angled arrow marked L indicates the direction of the longitudinal extension motion of the inner flexible needle 4, to access the off-axis region of the brain which it is desired to treat. In order to provide access to any part of the entire three-dimensional volume of the region to be treated, i.e. including cross-sections out of the plane of the drawing, it is necessary to activate motor 5 in order to rotate the complete combined needle assembly by rotating base section 2, as indicated by the rotation arrows, marked R in Fig. 3. The robotic control system, using the dimensional extent of the region to be treated as determined by the preoperative three-dimensional images generated of the region, coordinates motion of all three motors in order to gain access to any part of the entire three-dimensional volume. Thus, a specific target area is reached by combination of (i) the orientation angle of the cannulated needle 3, such that its distal opening is directed towards the target area, (ii) the depth of entry of the cannulated needle 3, and then (iii) the extension of the flexible needle 4, to reach the target area.

In Fig. 1A to 3, and the corresponding Fig. 5 later in the disclosure, the base section 2 is shown as a large baseplate covering much of the extent of the main base 1. However, it is to be understood that the so-called base section
through which the internal and external needle assembly is axially mounted and rotates therewith, may be no more than a collar mounted on the external needle assembly, with a robotic mechanism for rotating the collar relative to the main base fixed to the subject's skull. The invention is not therefore intended to be limited by the type of rotating base section shown in Fig. 1A, the operational feature being that that element be capable of controllably rotating the needle assembly around its axis.

As an alternative to accessing the lateral (longitudinal) extent of the volume to be treated by means of the extension of the internal needle 4 through a fixed angle exit port in the outer rigid cannular needle 3, it is possible to direct the angle at which the inner flexible needle is extended into the cerebral tissue, by means of an adjustable angle exit port incorporated into the external rigid cannula. One such implementation is shown in Fig. 4A, which is an enlarged isometric drawing of the bottom end of the double needle assembly. According to this implementation, the bottom end of the external cannular needle 3 is provided with a variable angle exit aperture, through which the internal flexible needle 4 can protrude. This exit aperture can be in the form of a pair of pins 26 attached to a rotatable pulley 28. The pins act as jaws which constrain the outer surface of the internal needle 4, and direct it to the desired angle as the pulley 28 is rotated. The angle of the exit aperture can be conveniently be adjusted for instance by means of a pair of drive wires 27 looped around the pulley 28. The outer cannula 3 should be extended to cover the outer diameter of the pulley wheel and to enclose its distal end, to ensure smooth insertion of the device, without the pulley wheel or its pins causing unnecessary damage to the cerebral tissue. A slit can be formed in the rounded distal cover of the pulley wheel to enable the inner flexible needle to exit the cover at the desired angle.

In use, the robotic device should be inserted into the subject's cerebral tissue with the pulley positioned such that the pins are in their lowermost position (in the sense of the directions shown in the drawing), in line with the axis of the external cannula, and with the inner flexible needle extended far enough for its distal end to just be captured between the pins. The pulley may then be rotated until the pins and the tip of the internal flexible needle held within the confines of the pins are rotated to such an angle that the flexible needle is directed to extend in the direction predetermined to reach the intended target region. Once this
angular orientation has been achieved, the inner flexible needle can be extended outwards from the outer rigid cannula, to access the region to be treated.

As an alternative to a pulley wire with pins, reference is now made to Fig. 4B which illustrates a rotatable block 30 with a channel 31 formed therein mounted within the distal end of the outer cannular needle 3. The inner flexible needle 4 can be guided into the channel 31 while it is aligned axially with the bore of the cannulated needle, and the block can then be robotically oriented to the desired angle required to direct the internal flexible needle to the desired point in the subject's brain. The center of rotation of the guide block 30 should be near its proximal end so that the entrance to the channel 31 remains fairly centrally located within the cannulated needle 3, to enable smooth entry of the flexible needle 4. The robotically controlled drive motor for pulling the pulley wires to adjust the angle of this exit aperture, or to rotate the angularly variable channel block, can then be used in lieu of, or in addition to, the drive motor 6 for inserting the external cannula, while performing the surgical procedure. By this means additional flexibility or additional simplicity, is available for gaining access to perform the procedure. Thus for instance, the external cannular motor 6 can be used for advancing the operating end to the most proximal point of the region to be treated, and the treatment itself performed by means of the variable angular exit aperture of the internal needle and the exposure extent of the internal needle, as shown by the set of arrows at the tip of the internal flexible needle, together with, of course azimuthal rotation of the entire robot activation arm. According to this implementation, with the tip of the external cannular needle at the top of the treatment region, the pulley needs to cover an angular range sufficient for covering the entire region to be treated.

The implementations of Figs. 4A and 4B are illustrated using a pulley wheel with wires operated externally to rotate it, since such an arrangement can be readily installed within the confines of the cannular needle 3, but it is to be understood that any other form of rotation that does not unduly increase the outer diameter of the device can alternatively be used.

The angle though which the flexible needle can be delivered, whether use is made of the fixed angle exit port of Figs. 1 to 3, or the variable angle exit port of Fig. 4, is dependent upon the flexibility of the inner needle and on its diameter. The more flexible the needle, the greater the angle that can be negotiated, and
the thinner the needle, the greater the angle that can be negotiated. A compromise must be made between the need to maintain sufficient stiffness in the flexible inner needle to enable it to reach its planned target without being deflected, and the need for it to readily deploy from the angled outlet port at the end of the rigid outer cannula.

It is to be understood that the specific embodiments shown in Figs. 1 to 4B are only possible examples of how to implement the robotic neurosurgical systems described in the present application, and that they are not intended to limit the scope of the invention of the present application, which is based on the use of a pair of concentric needle elements for accessing the region to be treated, even if in the depth of the brain, by means of a small incision and a narrow access path. The outer one is a rigid guide element and the inner one is a flexible operating element - flexible such that it can be directed out of the inner guide at a desired angle, and an operating element because it is equipped with the desired tool for performing the surgical or diagnostic procedure to be undertaken. Access to any part of the region to be treated is provided by combinations of motion of the inner and outer elements.

Use of the device according to any of the above described implementations, thereby enables the execution of comparatively large volume procedures within the interior of the brain, yet without causing more trauma to the rest of the brain than that of the insertion of the external cannula along its narrow path. Thus, use of the robotic neurosurgical device of the present application, using minimal access from a small burr hole in the skull, enables the treatment of a substantially large volume of the brain with minimal collateral trauma to those parts of the brain not being treated. Furthermore, because of the simplicity of the access method used, the surgeon can choose the access path such that it causes least trauma to the other parts of the brain, even though that path may be longer than the closest path from the skull to the region to be treated.

As previously mentioned, treatment of the desired region can be accomplished either by means of a cutting instrument at the distal end of the internal needle, or by means of an electric current, or by ablation by means of energy delivered down the internal needle, or by means of drug delivery to any or all parts of the region to be treated. Delivery of heat or light can be very advantageously performed using fiber optical delivery, with the optical fiber either
replacing the internal needle completely, or being threaded through the internal
needle, with its termination at the tip of the internal needle. Additionally, biopsies
of any part of the region be treated can be simply executed using biopsy pincers
at the end of the internal needle.

Reference is now made to Fig. 5, which illustrates schematically a complete
practical robotic system based on the above described implementations, including
a number of safety features required by such a system for performing
neurosurgery. In the first place, in order to define the position of the robotic
system activation arm relative to the position of the region to be treated, as
determined from preoperative three-dimensional images, some registration
features must be provided. In the presently shown implementation, this is
achieved by the provision of preferably three or more pins 17, 18, inserted into the
skull preoperative\(^{\text{a}}\), such that their position is uniquely defined in the preoperative
three-dimensional images. These pins are inserted at positions which are
predefined to match the mounting holes in the main base 1 of the robotic system,
such that when the system is mounted on these pins, its position is registered
relative to the data of the preoperative three-dimensional images. The robotic
control commands to the distal end of the internal needle of the activated arm can
thus be related to the position of features shown in the preoperative three-
dimensional images.

In addition in Fig. 5 there are shown back-up sensors and encoders for
every motion function of the robotic system, as required by the safety regulations
for use of such systems. Thus for instance the physical position of the internal
flexible needle may be determined by primary 10 and secondary 11 encoders,
while the electronically determined position of the motor driving the internal flexible
needle may be determined by primary 8 and secondary 9 encoders. Additionally,
the physical position of the external rigid cannular needle may be determined by
primary 13 and secondary 14 encoders, while the electronically determined
position of the motor driving the external rigid cannular needle may be determined
by primary 15 and secondary 16 encoders. Furthermore an encoder 12 for the
rotating platform angular position is also provided. This encoder also generally has
a back-up (not shown in Fig. 5). The encoders described in this disclosure may
include optical, magnetic, electrical, or inductive encoders. All of the sensors,
motors and encoders are connected to the robotic controller, which, for simplicity, is not shown in Fig. 5.

Additional sensors can be incorporated at the distal end of the flexible needle, to provide additional information or additional guidance to the surgeon. Thus, in Fig. 5, there is shown a representation of an electrophysiological or optical sensor 19, for tissue diagnosis. In addition, an ultrasound sensor can be added, such that it detects the needle location in real time as well as the boundaries of the diseased area. The ultrasound sensor can be located either on the flexible needle 19, or on the external rigid cannula 23. In the latter case the ultrasound sensor can sense both the flexible needle tip as well as the tumor boundaries. It is sufficient to detect only the diseased area boundaries, as the relative position between the flexible needle tip and the rigid needle mounted ultrasound sensor is known from the robot control system. An infra red sensor that can detect and distinguish tissue properties some distance inside a tissue can alternatively be used for this purpose. Such optical sensors can detect, for instance, fluorescence effects in tissues, to label specific types of cell to which the appropriate fluorescing drug attaches. Similarly, an electric sensor that can detect the differences in electric properties between healthy and diseased tissue can be added to the needle tip.

Furthermore, the camera of an imaging system 25 is shown in Fig. 5, such that intraoperative images of at least some of the region 22 of the brain being treated, the needle tips, the main base 1 and its skull locating elements 17, 18, can be obtained, most advantageously together with anatomic features of the subject's skull and/or face. Such images can be used for monitoring the position of the needle tips, and for providing information for performing a registration of the robotic device with the preoperative images available.

Finally, reference is now made to Fig. 6, which illustrates schematically further exemplary implementations of the needle insertion devices described in this disclosure. In Fig. 6 there is firstly shown an alternative method of fixing the robotic device of the present application to the skull 60 of the patient being treated. This is illustrated in Fig. 6 using a phantom skull only in order to show the fixation method. Instead of being attached by means of a base unit which is screwed directly into the skull of the patient, as is shown in the previous implementations, in Fig. 6, the needle insertion system is supported on a
stereotactic frame 61, of any type that is known in the art, though any other type of frame defining the position of the robotic device relative to the skull may also be used. As an alternative to a stereotactic frame, a Mayfield clamp may alternatively be used, though in this case, there will be need to perform a registration procedure in order to define the position of the clamp and the device attached thereto to the preoperative images, such as by surface feature matching or fiducial markers. In the implementation shown in Fig. 6 the angular alignment scale 62 is shown for only one azimuthal orientation, but it is to be understood that the other two azimuthal orientations also have scales to enable alignment to be made in those angular directions too. The device is attached by means of a rotatable base unit 63, and the needle assembly 3, 4, with its robotic controls 6, 7 are inserted through this rotatable base assembly in a similar manner as in the previous embodiments of Figs. 1A to 5.

Fig. 6 also illustrates an alternative use of the device of the present disclosure, to improve prior art methods of determining the direction of penetration of a treatment needle used in neurosurgery. In such a prior art methods, the region to be treated is defined on preoperative images, which include the mounting hardware used to support the needle insertion device. This mounting hardware could be the relevant parts of a stereotactic frame or of a Mayfield clamp. The surgeon then defines the orientation angles and depth of penetration of the needle, using the alignment facilities provided on the mounting hardware. Since the same mounting hardware is registered in the preoperative images, the surgeon can then access the intended target using calculated angles and depths for that mounting hardware. Using prior art methods of a single needle inserted straight into the patient's brain, there may be situations where access to the target point is problematic because of sensitive or damage prone regions of the brain in the direct linear access path.

According to an alternative use of the system of Fig. 6, where a stereotactic frame implementation is illustrated, the same registration procedure can be used as described above, but instead of aligning the prior art linear entry needle directly at the target, the surgeon can use the present device to circumvent any regions on the linear path where access is contraindicated. In use, the surgeon may plan an "articulated" safe entry path, using the pre-operative images. The surgeon then aligns the needle assembly 3, 4, in the correct angular directions, using the head
clamp scales 62, and the graduated base scale 63 of the device, and then actsuates the entry procedure described above in connection with the embodiments of Figs. 1A to 5, firstly inserting the external cannular needle 3, using the drive motor 6, and then, deploying the flexible needle 4, using the drive motor 7. As an alternative, a variable opening cannular needle can be used as described in Figs. 4A and 4B. The device is thus able to access in two dimensions, locations which would otherwise be problematic to reach by a direct linear path. The specific target area is reached by controlled combination of (i) the depth of entry of the cannulated needle 3, and then (ii) the extension of the flexible needle 4, to reach the target area.

It is appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of various features described hereinabove as well as variations and modifications thereto which would occur to a person of skill in the art upon reading the above description and which are not in the prior art.
We claim:

1. A robotic device for performing intracranial procedures, comprising:
   - a baseplate adapted for mounting on the skull of a subject;
   - a rotatable element disposed on said baseplate, and having an opening in its central region;
   - a first, cannulated needle mounted on said rotatable element coaxially with said opening, and which rotates with rotation of said rotatable element, said first cannulated needle being robotically controlled to provide motion into and out of the skull of said subject; and
   - a second, flexible needle disposed in said first cannulated needle, said second flexible needle being controlled to provide motion into and out of a non-axial aperture in the distal part of said first cannulated needle;
   wherein coordinated control of the insertion motion of said first and second needles and rotation of said rotatable element enables access to be obtained by said second flexible needle to a target region of the brain where said procedure is to be performed.

2. A robotic device according to claim 1 wherein said target region accessed by said device may have lateral dimensions substantially larger than the width of said first cannulated needle.

3. A robotic device according to either of the previous claims, wherein said device is adapted to provide said access to said target region of the brain with collateral trauma to non-accessed parts of the brain being approximately confined to a region having the width of said first cannulated needle.

4. A robotic device according to any of the previous claims, wherein said target region of the brain is located in a region of the brain where a direct access path from an external insertion point would pass through a region of the brain subject to damage by said flexible needle.
5. A robotic device according to any of the previous claims, wherein coordinated control of the insertion motion of said cannulated and flexible needles and rotation of said rotatable element enables access to be obtained by said flexible needle to said target region of the brain along an articulated path selected to avoid damage-prone regions of the brain.

6. A robotic device according to any of the previous claims wherein said second flexible needle comprises a cutting tool, such that resection of a brain tumor can be performed with collateral trauma to those parts of the brain not being treated being approximately confined to a region having the width of said first cannulated needle.

7. A robotic device according to any of claims 1 to 5, wherein said second flexible needle is adapted to be connected to an energy delivery system, such that ablation or electro-treatment of a brain tumor can be performed with collateral trauma to those parts of the brain not being treated being approximately confined to a region having the width of said first cannulated needle.

8. A robotic device according to claim 7 wherein said energy is any one of thermal, electrical, optical or ultrasound energy.

9. A robotic device according to claim 7, further comprising an optical fiber disposed within said second flexible needle for delivery of said thermal or optical energy.

10. A robotic device according to claim 9, wherein said second flexible needle is an optical fiber for delivery of said thermal or optical energy.

11. A robotic device according to any of claims 1 to 5 wherein said second flexible needle comprises a biopsy tool, such that biopsy samples may be obtained from regions of the brain at different positions laterally displaced from each other by distances substantially larger than the width of said first cannulated needle, with collateral trauma to those parts of the brain not being accessed being
approximately confined to a region having the width of said first cannulated needle.

12. A robotic device according to any of claims 1 to 5, wherein said second flexible needle comprises a drug delivery passage, such that a drug can be delivered to regions of the brain at different positions lateral displaced from each other by distances substantially larger than the width of said first cannulated needle, with collateral trauma to those parts of the brain not being accessed being approximately confined to a region having the width of said first cannulated needle.

13. A robotic device according to any of the previous claims wherein said non-axial aperture in the distal part of said first cannulated needle is a hole in the wall of said first cannulated needle.

14. A robotic device according to any of the previous claims wherein said non-axial aperture in the distal part of said first cannulated needle is an opening having a robotically directed variable angle exit aperture at the end of said first cannulated needle.

15. A robotic device according to any of the previous claims, further comprising a set of preoperative inserted markers for relating the position of said robotic device to the skull of a subject, such that the co-ordinate system of said robotic device can be registered to a preoperative image of the skull of said subject.

16. A robotic device according to any of the previous claims, further comprising at least one position sensor disposed in the distal region of said second flexible needle, such that the real time position of said second flexible needle tip can be monitored intraoperatively.

17. A robotic device according to any of claims 1 to 15, further comprising at least one position sensor disposed in the distal region of said first, cannulated needle, such that the real time position of said first cannulated needle tip can be monitored intraoperatively.
18. A robotic device according to any of the previous claims, further comprising an imaging system, such that the real time position of at least one of the first cannulated needle tip, and the second flexible needle tip can be monitored intraoperatively.

19. A robotic device according to any of the previous claims, further incorporating a sensor capable of detecting the boundaries between healthy and tumor tissues, and wherein such robotic device is adapted to use information regarding said boundaries to control the motion of said flexible needle.

20. A robotic device for performing neurosurgical procedures at a target region of the brain, comprising:

- a baseplate adapted for attaching in a predetermined orientation and position on the skull of a subject;
- a cannulated needle mounted on said baseplate, said cannulated needle having a non-axial aperture in its distal part, and a motion controller to provide motion into and out of the skull of said subject; and
- a flexible needle disposed in said cannulated needle, said second flexible needle having a motion controller to provide motion into and out of said non-axial aperture in the distal part of said cannulated needle;

wherein coordinated control of the insertion motion of said cannulated and flexible needles enables access to be obtained by said flexible needle to said target region of the brain along an articulated path selected to avoid damage-prone regions of the brain.

21. A robotic device according to claim 20 wherein said target region accessed by said device may have lateral dimensions substantially larger than the width of said first cannulated needle.

22. A robotic device according to either of claims 20 and 21, wherein said device is adapted to provide said access to said target region of the brain with collateral trauma to non-accessed parts of the brain being approximately confined to a region having the width of said first cannulated needle.
23. A robotic device according to any of claims 20 to 22, wherein said target region of the brain is located in a region of the brain where a direct access path from an external insertion point would pass through a region of the brain subject to damage by said flexible needle.

24. A robotic device according to any of claims 20 to 23, wherein adjustment of the predetermined orientation and position of the baseplate on the skull of a subject and coordinated control of the insertion motion of said cannulated and flexible needles enables access to be obtained by said flexible needle to said target region of the brain along an articulated path selected to avoid damage-prone regions of the brain.

25. A robotic device according to any of claims 20 to 24 wherein said second flexible needle comprises a cutting tool, such that resection of a brain tumor can be performed with collateral trauma to those parts of the brain not being treated being approximately confined to a region having the width of said first cannulated needle.

26. A method of performing intracranial procedures, comprising:

- providing a baseplate and mounting it on the skull of a subject, said baseplate having disposed on it a rotatable element with an opening in its central region;
- mounting on said rotatable element, coaxially with said opening, an assembly comprising:
  - a first, cannulated needle which rotates with rotation of said rotatable element, said first cannulated needle being robotically controlled to provide motion into and out of the skull of said subject; and
  - a second, flexible needle disposed in said first cannulated needle, said second flexible needle being controlled to provide motion into and out of a non-axial aperture in the distal part of said first cannulated needle;
- coordinating the rotation of said rotatable element and the sequential insertion of said first and second needles to enable access to be obtained by said
second flexible needle to a target region of the brain where said procedure is to be performed.

27. A method of performing neurosurgical procedures at a target region of the brain, comprising:
   attaching in a predetermined orientation and position on the skull of a subject, a base element;
   mounting on said base element, an assembly comprising:
   a cannulated needle, said cannulated needle having a non-axial aperture in its distal part, and a motion controller to provide motion into and out of the skull of said subject; and
   a flexible needle disposed in said cannulated needle, said second flexible needle having a motion controller to provide motion into and out of said non-axial aperture in the distal part of said cannulated needle;
   selecting on a preoperative image of said brain, a singly articulated path avoiding damage-prone regions of the brain; and
   controlling the sequential insertion motion of said cannulated needle and said flexible needle to enable access to be obtained by said flexible needle to said target region of the brain along said singly articulated path.
INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 12/00022

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61 B 19/00 (2012.01)
USPC - 606/130

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC8 : A61B 19/00 (2012.01)
USPC : 606/130

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC8 : A61B17/00, 17/34, A61M25/00, 25/06 (2012.01)
USPC : 604/19, 604/48, 604/93.01, 604/264, 604/272, 606/1, 167, 184, 185, 190

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST/IPGBP, USPTO/PAB, Google: surgical, surgery, plan, route, atraumatic, none, minimal, reduce trauma, lateral, side, nonaxial angle, deflect, opening, port, window, trajectory, guide, flexible, flex, bend, probe, needle, tool, instrument, cannulated, hollow, lumen, base, baseplate, mount, frame, platform, intracranial, brain, cerebral, ac

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>Y</td>
<td>US 2009/0048610 A1 (TOLKOWSKY et al) 19 February 2009 (19.02.2009) see especially para [0024],[0034],[0037], fig 1, 3, 10-12</td>
<td>1-3, 20-22, 26-27</td>
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Further documents are listed in the continuation of Box C.

Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search
3 May 2012 (03.05.2012)

Date of mailing of the international search report
25 MAY 2012

Name and mailing address of the ISA/US
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Authorized officer:
Lee W. Young
PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)
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<td>1. [ ] Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:</td>
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<td>2. [ ] Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:</td>
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<td>3. [x] Claims Nos.: 4-19, 23-25 because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).</td>
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<td>4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:</td>
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**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/2 10 (continuation of first sheet (2)) (July 2009)