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ORIGINAL ARTICLE

Customized, rapid-production microstereotactic table for surgical targeting: description of concept and in vitro validation

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Abstract
Purpose To introduce a novel microstereotactic frame, called the Microtable, consisting of a tabletop that mounts on bone-implanted spherical markers. The microtable is customized for individual patient anatomy to guide a surgical instrument to a specified target.
Methods Fiducial markers are bone-implanted, and CT scanning is performed. A microtable is custom-designed for the location of the markers and the desired surgical trajectory and is constructed using a computer-numerical-control machine. Validation studies were performed on phantoms with geometry similar to that for cochlear implant surgery. Two designs were tested with two different types of fiducial markers.
Results Mean targeting error of the microtables for the two designs were 0.37 ± 0.18 and 0.60 ± 0.21 mm ($n = 5$). Construction of each microtable required approximately 6 min.
Conclusions The new frame achieves both high accuracy and rapid fabrication. We are currently using the microtable for clinical testing of the concept of percutaneous cochlear implant surgery.

Keywords Stereotactic frame · Image guidance · Fiducial · Cochlear implants

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Introduction

Image-guided surgical (IGS) technology allows surgeons to navigate based upon registration of pre-intervention images (e.g., CT or MRI scans) to intraoperative anatomy. In the last 15 years, IGS systems using real-time tracking of surgical instruments have been FDA-approved and CE-marked for endoscopic sinus surgery and neurosurgical intervention. While versatile in allowing free-hand navigation during surgery, the accuracy of such IGS systems depends upon the type and placement of fiducial markers used to register to the pre-intervention scans. Accuracy of systems range from 1 to 2 mm for those which utilize bone-implanted fiducial markers [1] to 2–5 mm for those which depend upon skin-affixed fiducial marker systems (e.g., adhesively affixed skin markers and laser scanning of skin surfaces) [2].

For clinical applications where only a single or finite number of targets are to be accessed, the use of a highly versatile, real-time tracking IGS system may not offer the best solution. For such applications—biopsy and/or placement of electrodes into precise intracranial locations—the traditional stereotactic frame provides better overall accuracy without the need for elaborate tracking systems. The stereotactic frame is rigidly attached to a patient during both imaging and surgical intervention using sharp pins that pierce the skull. It offers increased levels of accuracy because the frame provides both the fiducial system and the targeting system. To date the most successful fiducial component of the stereotactic fame is the N-frame of Brown's design [3]. Target locations are determined by triangulation relative to the N-frame. Accuracy for such traditional stereotactic frames approaches 1 mm or better [4–6]. However, a major drawback is the bulky nature of the frames which are extraordinarily uncomfortable for patients and often obstructive of surgical exposure in the operating room.

To overcome the drawbacks of traditional stereotactic frames, microstereotactic frames were introduced. One such frame is a patient-customized microstereotactic frame [7] that mounts on bone-implanted anchors, which serve also as fiducial markers for targeting purposes. Now commercially available, the "StarFix microTargeting Platform" (FHC Inc., Bowdoin, ME, USA), henceforth referred to as the Starfix, is FDA-approved for placement of deep brain stimulating (DBS) electrodes [8]. In practice, a patient has at least three bone-implanted anchors placed, following which a CT, and possibly an MRI, is obtained. These fiducial markers are small and subcutaneously placed, so the patient can leave the medical facility between imaging and surgical intervention and return to normal activities of daily living. In the patient's absence, the surgical target is identified, as a path from the surface of the skull to the target. Next, a microstereotactic frame that mounts on the anchors and achieves the desired trajectory is manufactured via rapid prototyping. Because rapid-prototyping technology requires expensive equipment and expertise to perform, the current paradigm employs a centralized manufacturing facility from which the customized frames are shipped. Shipping imparts a delay of at least 48 h from the time of anchor placement until the time of surgical intervention. This delay is a disadvantage relative to the traditional stereotactic frame, but holds out the benefit of decreased human error as no adjustments are necessary once the Starfix is mounted. A recent phantom study indicated that the Starfix as used for DBS surgeries, provides submillimetric accuracy [9].

Another microstereotactic frame FDA-approved for DBS surgeries is the "NexFrame" (Medtronic, Minneapolis, MN, USA) [10]. Unlike the Starfix, which is custom built for each patient, the NexFrame is universally adaptable to patient anatomy through the use of a real-time tracking IGS system, which is necessary to localize fiducials and aim the device. While the NexFrame system can be used immediately after placement of markers and CT/MRI scanning, it requires the availability of an IGS system, which costs upwards of $100,000. Resultant accuracy is limited by the tracking error inherent to the IGS system and human error during alignment of the device. A recent phantom study indicated that the NexFrame provides accuracy on the order of just over one millimeter [11].

In this paper we introduce a new microstereotactic frame, which combines the advantages of both the Starfix and the NexFrame systems, while overcoming each system's disadvantages. We term this stereotactic device a "Microtable". Like the Starfix, the microtable is customized in a rigid form for each patient, minimizing human error in clinical application. Like the NexFrame, the microtable is customized on site thus eliminating the turnover time of the Starfix. Herein we present the concept as well as phantom testing mimicking one proposed clinical use—surgical targeting of the cochlea to place a cochlear implant electrode. Our phantom testing shows submillimetric accuracy for this application.

Materials and methods

Our goal is to reach a surgical target at the end of a specified linear trajectory. For simplicity, we define this surgical task with two points—a target and an entry point. For building a microstereotactic frame that constrains a device to follow this path, a coordinate reference system needs to be defined in order to specify the relationship of the patient's anatomy to the frame. For this purpose, we use a set of spherical fiducial markers, which are implanted in bone surrounding the target of interest, as a frame of reference around which all calculations can be made. The unique and central concept to the microtable is that these spheres are used to support a miniature tabletop that can be made perpendicular to the desired trajectory by specifying the length and orientation of each table leg. We chose a design in which the legs are parallel to the trajectory, which simplifies the fabrication but is not a requirement. Following this, the trajectory is located on the tabletop in reference to the legs. This central concept is shown in its simplest implementation in Fig. 1a. To provide clearance above soft tissue, the spherical fiducial markers may be fit with extenders as shown in Fig. 1b. The symmetry of the spherical fiducial markers allows them to be attached to the bony anatomy with anchors at relatively arbitrary locations and orientations.

Figure 2 shows the steps involved for a clinical application. The steps in detail are as follows.

1. Implant markers—anchors are implanted into bone surrounding the surgical target of interest. For the current cochlear-implant application, three anchors are placed in the mastoid bone surrounding the cochlea as shown in Fig. 3. Extenders are attached to the anchors with spherical fiducial markers of 1/4 inch (6.35 mm) diameter at their ends. The extenders and fiducials are fashioned of CT-compatible materials. The patient is under general or local anesthesia, depending on the application.
2. Acquire CT scan—a clinically applicable CT scan is obtained spanning the surgical target and all the markers.
3. Localize centers of markers—the centers of the spheres are localized in the radiographic image by means of algorithms that find their intensity centroids.

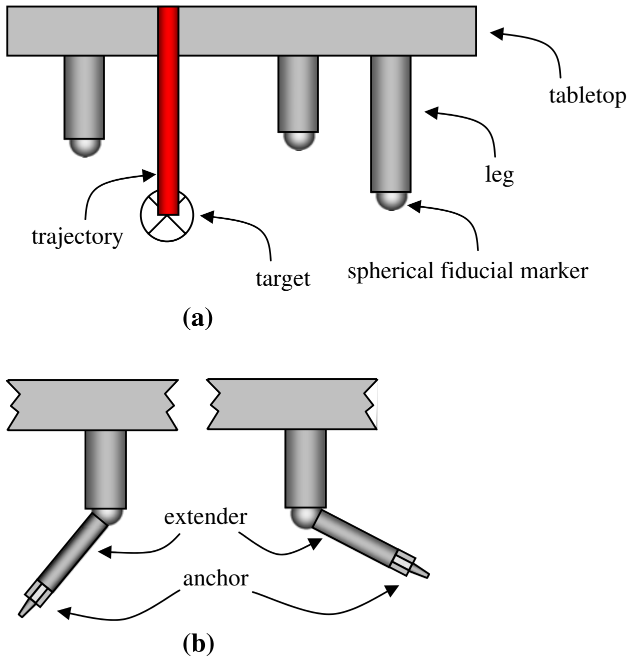


Fig. 1 **a** In the simplest implementation of the microtable concept, three spherical fiducial markers are used. The tabletop is elevated above the spherical fiducial markers using legs to orient it perpendicularly to the trajectory. **b** Two example configurations of bone-implanted anchor and extender for the spherical fiducial marker illustrating that specific location and orientation of the anchors are relatively unimportant

4. Perform path planning—the target and entry points defining a trajectory are chosen in the CT image. This step can be performed in parallel to the localization of the markers. A fixed distance from the target is chosen as the length of the trajectory. For our application, this distance is chosen as 75 mm.
5. Custom design the microtable—a customized virtual model of the microtable is created automatically by planning software written in Matlab (The Mathworks, Natick,

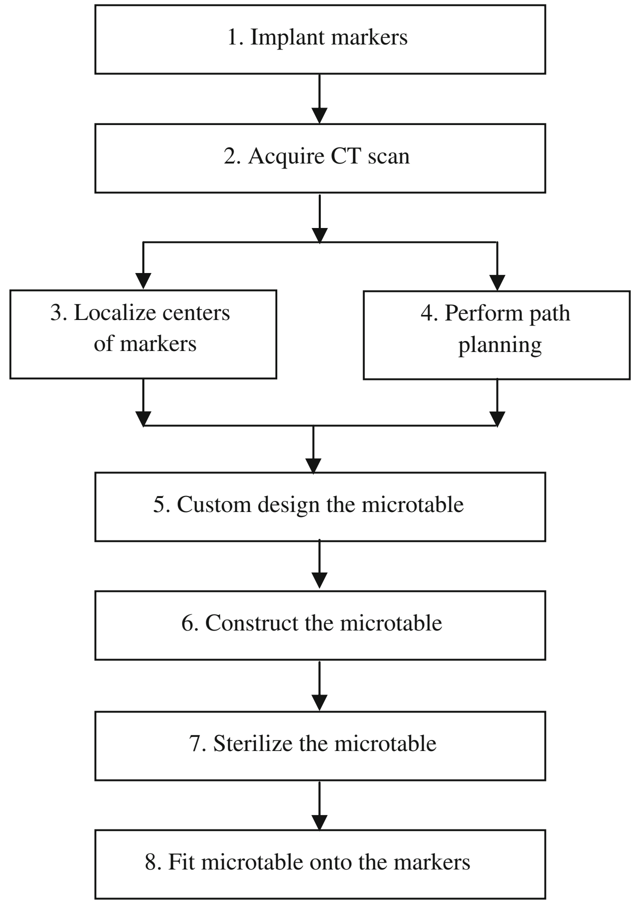
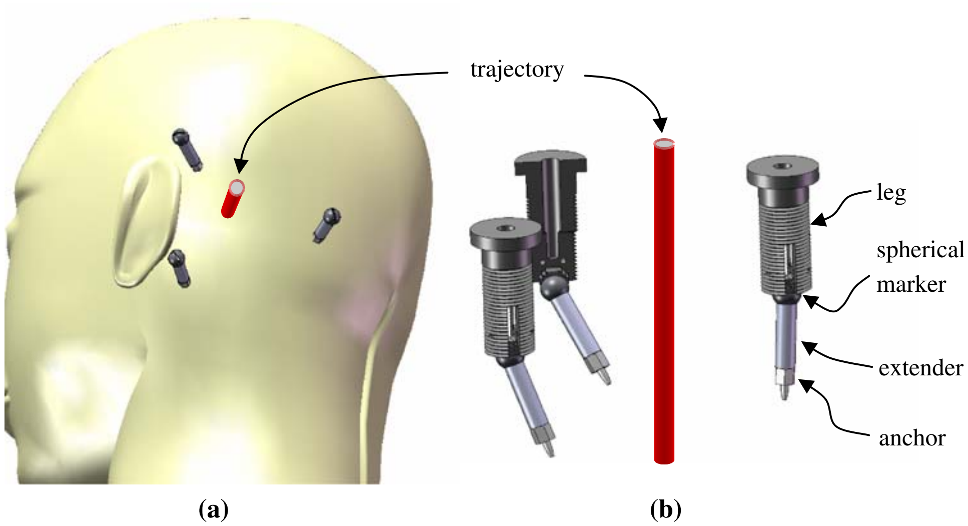


Fig. 2 Flowchart explaining steps involved for clinical application

MA, USA). The input to the software is the location of the markers as determined in Step 3 and the trajectory as specified in Step 4.

The z-axis is defined to be coincident with the trajectory with origin 75 mm above the surgical target and lying

Fig. 3 **a** Spherical fiducial markers atop extenders anchored to the skull; **b** Legs attached to spherical fiducial markers. The planned trajectory is shown as a *red* cylinder



on the upper surface of the table. The thickness of the table is selected based on the proposed application. In our application, we use a thickness ranging from 0.7 to 1 inch. Legs extending from the tabletop to the spherical markers are chosen from a finite set of lengths (we use a set of three) such that, when the foot of a leg mates with its sphere, its distal end falls within the thickness of the tabletop.
After creating the customized model, the planning software automatically generates the commands in a numerical-control programming language (G-code) to produce the required tool paths to be executed by a computer-numerical-control (CNC) machine to form the tabletop.

6. Construct the microtable—under the guidance of the G-code, the CNC machine drills a hole for each leg through the tabletop perpendicular to its surface with countersinking that produces the correct depth of penetration of the legs, as calculated from the planning software, such that the tabletop is perpendicular to the trajectory and its distal surface is the required distance from the target (Fig. 4). In addition, the trajectory hole is drilled (Fig. 5).
Quality assurance is performed by inserting pins into the holes and measuring the outside-to-outside displacements of the pins relative to each other using calipers. The same is repeated at a specified height above the hole to check for parallelism. A notch on the pins at the specified height ensures repeatable measurements (Fig. 6). Once we confirm the dimensions, a two-piece cup/gripper assembly is inserted into each leg to secure each leg to its corresponding spherical fiducial marker (Fig. 7).
7. Sterilize the microtable—the assembly is flash sterilized and is ready for mounting on the patient in the procedure room.

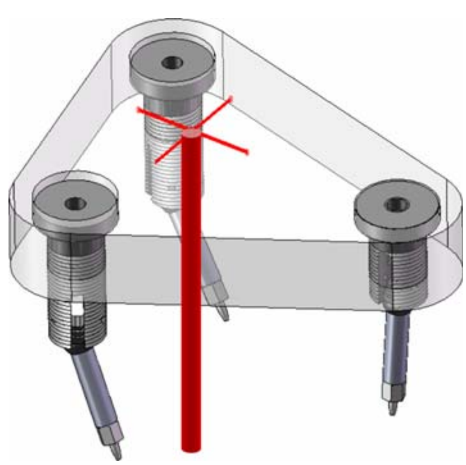


Fig. 4 Countersinking of the legs such that the tabletop is perpendicular to the trajectory

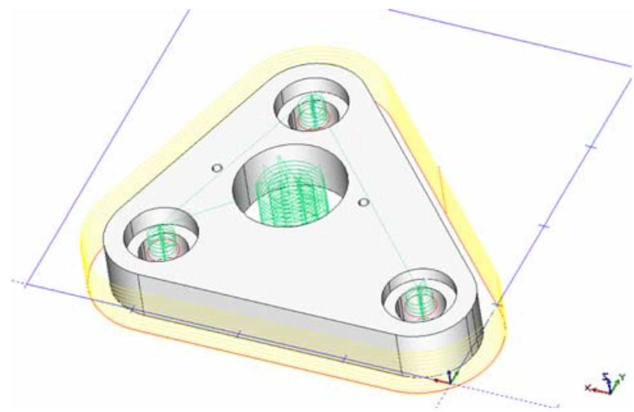


Fig. 5 Microtable with CNC tool paths shown in green

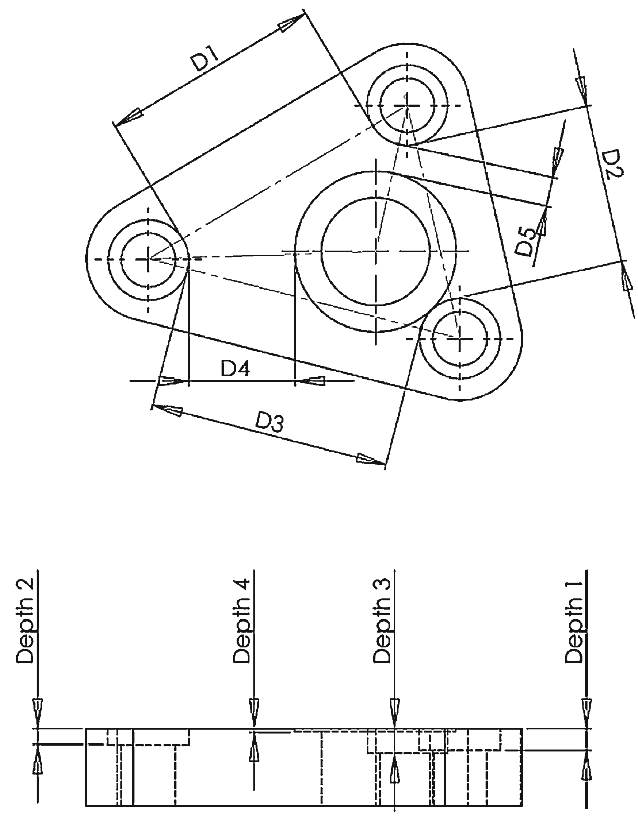


Fig. 6 Quality assurance by measuring distances between holes

8. Fit microtable on the markers—the microtable is affixed to the patient and a probe or drill is affixed to the platform in the trajectory hole (Fig. 8).

Phantom testing

The accuracy of the microtable can be analyzed using an approach previously used to validate the Starfix platform, as used for deep-brain stimulator placement [9,12]. The goal is to measure the accuracy with which a platform places the end

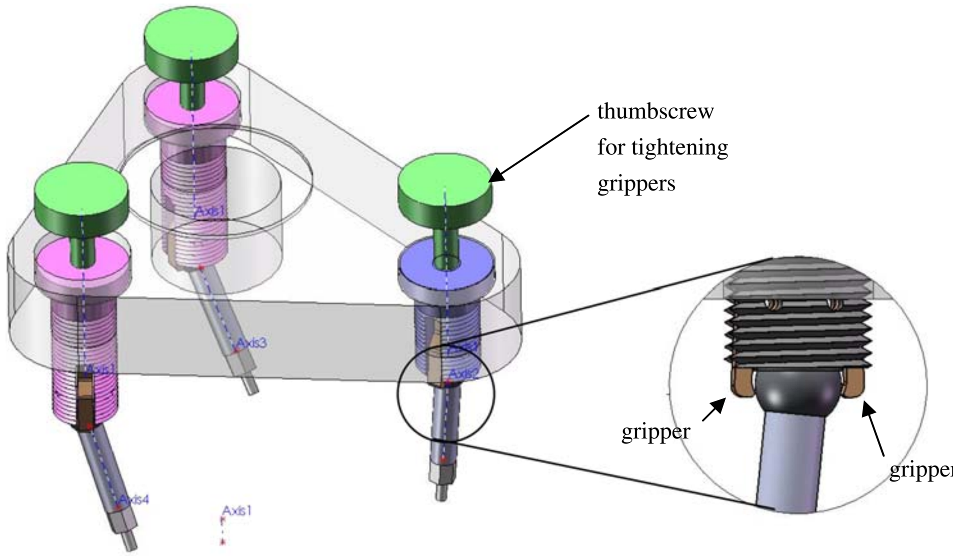


Fig. 7 Coupling mechanism between spherical fiducial marker and table leg. The inset shows a close up of one coupling. Twisting the thumbscrew tightens the grippers, thereby fixing the leg to the marker

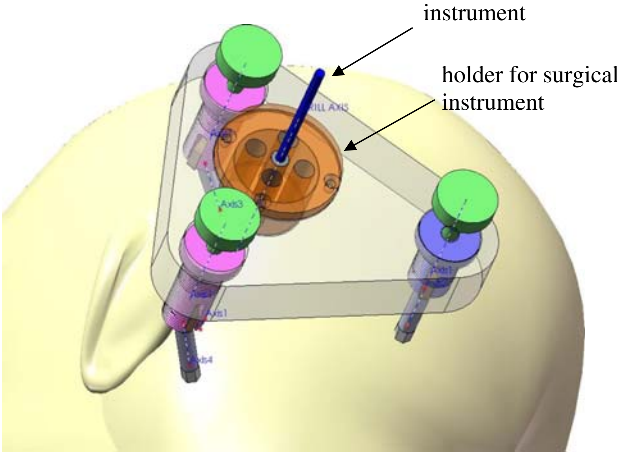
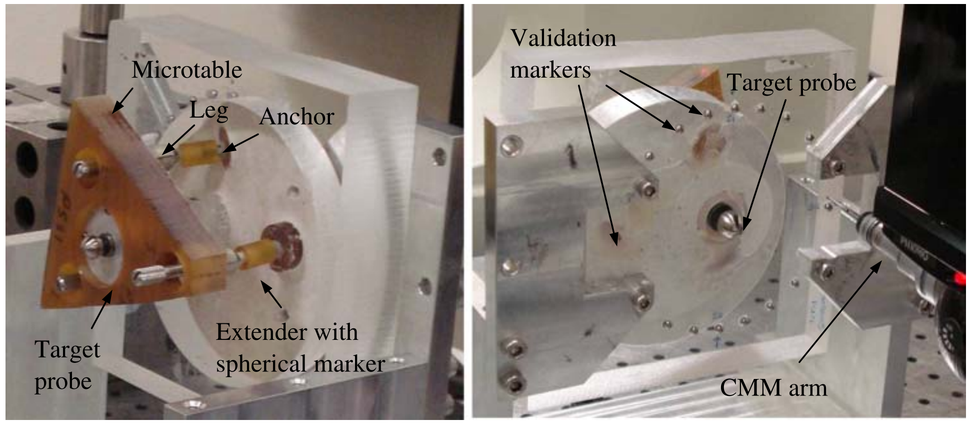


Fig. 8 Microtable attached to patient with surgical instrument attached via a holder to the tabletop and ready for procedural intervention

of a probe at a specified target using a clinically relevant phantom. Specifically, we measure the placement error, which we define to be the distance by which a probe placed in the trajectory hole of the platform misses its specified target. As part of the measurement process it is necessary to determine a transformation from image space to physical space, as the target is specified in image space but is targeted in physical space. This transformation is accomplished by means of an independent registration based on 16 spherical "validation" markers not used by the microtable. Details regarding this technique of error measurement and analysis can be found in [9,12].

Phantoms were built based on the anatomy of patients, who had been enrolled in a previously reported, clinical-validation test of microstereotactic frames as used in cochlear implant surgery [13]. Each phantom (Fig. 9) was made of an acrylic block with 16 validation markers surrounding the target and three spherical fiducial markers as used to create and mount the microtable as described in the steps above (see "Materials and methods"). Mounting anchors for the fiducials were immobilized by embedding them in epoxy cast. The locations of the spheres can be determined either by (1) directly identifying their centers via the CT scan or (2) determining the location and orientation of the anchors and estimating their position based on the length of the extender [14]. Option 1 has the theoretical advantage of higher accuracy by direct localization of the spheres. Option 2 has the advantage that the extenders and markers do not have to be in place for the CT scan, a clinically advantageous scenario.

Two clinically applicable CT scans were made for each phantom—Option 1 with spherical fiducial marker assemblies mounted on each anchor and Option 2 with only the anchors. The 16 validation markers were localized in both CT space (using intensity-based algorithms) and physical space (using a coordinate measuring machine (CMM) with an accuracy of 0.004 mm (Brown and Sharpe, Chameleon; Wright Industries, Nashville, TN; calibration 4/11/06; certificate 4112006029735005). These localized positions were then used to produce the required transformation from image space to physical space for specifying the desired physical target. The location of this desired target is then compared to that achieved using a probe mounted on the microtable. For the present application (i.e., placing electrodes into the cochlea), the probe was 75 mm in length. Microtables were made according to the CT scans using either Option 1 or 2 as described above. The 75 mm trajectory probe was sequentially mounted in each microtable and its position measured using the CMM. The error of each microtable was calculated as the distance from the desired target position to the



(a) (b)

Fig. 9 Phantom as used in coordinate measuring machine (CMM). **a** Microtable mounted on the spherical markers in a phantom. **b** Physical localization of spheres using the CMM

actual probe position. For each phantom, two microtables were analyzed—Option 1 and Option 2. The Option-1 microtable was mounted on the phantom first, as this option was expected to have better fit and less stress on the anchors, and hence less effect on the subsequent measurement for Option 2. The Option-1 microtable was removed after the measurements were done, and the Option-2 microtable was mounted. Option 1 and Option 2 were compared using the Wilcoxon signed-rank test because (a) the data sets were related since only the fiducial marker sets differed between the two options and (b) the limited number of data points ($n = 5$) precluded assuming a normal distribution population.

Results

Five phantoms were prepared for Option 1 and Option 2. The error values are reported in Table 1. For Option 1, the mean targeting error was 0.37 ± 0.18 mm ($n = 5$) with maximum error of 0.61 mm and minimum error of 0.20 mm. For Option 2, the mean targeting error was 0.60 ± 0.21 mm ($n = 5$) with maximum error of 0.91 mm and minimum error of 0.34 mm. Comparing results of these two options using the Wilcoxon signed-rank test showed a significant difference with Option 1 (spheres as fiducials) performing better ($p = 0.05$). Each microtable was constructed in approximately 6 min.

Table 1 Error measurements for the microtable

Phantom number	Option 1	Option 2
1	0.20	0.48
2	0.61	0.64
3	0.26	0.62
4	0.50	0.91
5	0.27	0.34
RMS	0.40	0.63
Mean ± SD	0.37 ± 0.18	0.60 ± 0.21
Max	0.61	0.91
Min	0.20	0.34

Units are mm. Option 1: location of spherical fiducial markers directly determined. Options 2: location of spherical fiducial markers determined based on anchors

Discussion

Contained herein are descriptions of, and accuracy studies of, a new microstereotactic frame based on spherical fiducial markers upon which a table is custom mounted to achieve a desired surgical trajectory. Using this device, which we have termed the “Microtable”, we performed phantom studies and report submillimetric accuracy in conditions similar to those encountered in the human temporal bone during cochlear implant surgery. Two fiducial options are described. The first uses the spheres as the fiducials markers, and the second uses the anchors to which they attach to the patient as the fiducial markers. Using the first option, we report a mean accuracy of 0.37 ± 0.18 mm ($n = 5$). To the best of our knowledge, this is the most accurate phantom testing yet reported for microstereotactic frames. Using the second option, we report an accuracy of 0.60 ± 0.21 mm ($n = 5$). Even in this less optimal configuration, the accuracy compares favorably with those reported for other microstereotactic frames [9,11]. The first option requires that the spheres be in place during the CT scan. Hence, it requires the availability of a portable CT scanner during the procedure.

Our work was motivated by the clinical goal of placing an electrode array into the cochlea via a single drill pass—a procedure known as percutaneous cochlear implantation. This radical approach to cochlear implant surgery avoids the larger surgery (mastoidectomy and posterior tympanotomy) that is the standard of care at present. We originally proposed this approach in 2003 and demonstrated the concept of using a customized IGS system to allow a surgeon to guide a drill along the specified trajectory [15]. During these original cadaver studies, we found that the free-hand approach allowed too much room for human error. We then moved to testing with microstereotactic frames, employing the StarFix microTargeting Platform first on cadavers [16] and subsequently performing safety testing during actual cochlear implant surgery [13]. During ongoing safety testing, we recognized that a major impediment towards clinical application has been the need to place bone-implanted fiducial markers prior to surgical intervention such that the microstereotactic frame could be constructed via the time-consuming, and ironically-termed, "rapid"-prototyping process. We hypothesized an idealized work flow in which (1) bone-implanted markers could be placed at the beginning of a surgical intervention, (2) CT images could be obtained with an intraoperative CT scanner, and (3) a customized, microstereotactic frame could be constructed in a timely fashion (e.g., <1 h after CT scanning, which is the approximate time needed for a mastoidectomy and posterior tympanotomy).

Thus, our goal was to custom build—in as short a time as possible—a rigid, customized, microstereotactic frame that achieves submillimetric accuracy. Simultaneously, we sought to do this economically. In addition to the unsurpassed accuracy, it is the combination of these two characteristics—speed and cost—that differentiate the microtable from others that are clinically available. As noted in the introduction of this paper, the two microstereotactic frames to which we are comparing the microtable are the StarFix microTargeting Platform and the NexFrame. The StarFix micro Targeting Platform has an impressive accuracy of 0.45 ± 0.15 mm for even deeper targets (120 mm) [9], but it takes hours for fabrication via rapid prototyping technology. The current workflow for a Starfix includes electronic transmission of data sets to a centralized manufacturing facility. As a result, in clinical practice the Starfix platform has a minimum 48-h turn-around time. The NexFrame, though it does not impose this time delay, requires intra-operative adjustments with the help of an expensive IGS system.

Unique to the microtable described herein is its capability for rapid targeting, resulting from the simple expedient of drilling a set of parallel holes through a single planar tabletop, which then mounts to a set of standardized table legs. Fabrication of the tabletop is the only varying component in the production of a microtable. Tabletop customization is achieved by drilling holes of specified depth and radius at the precise location at which the legs intersect the tabletop. To do this, as described in the "Materials and methods" section, we utilize a CNC milling machine. However, the versatility of a milling machine is in fact not required for this relatively simple application. A drill press combined with an x-y positioning table could achieve the same results. By

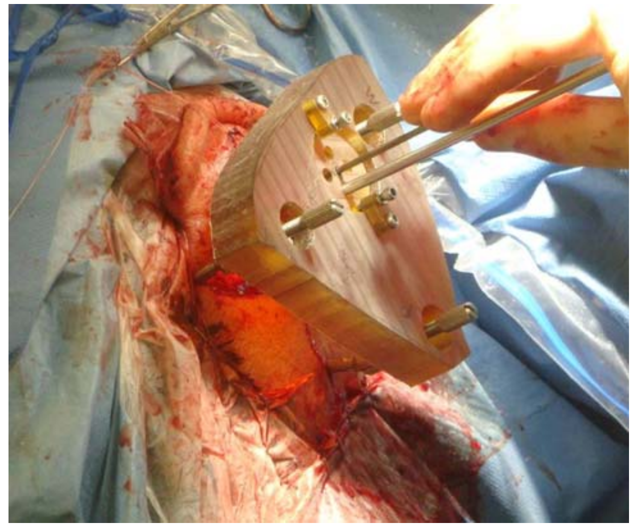


Fig. 10 Microtable mounted on the patient's head for validation. The Microtable was fabricated intraoperatively for cochlear implantation for the patient

using a CNC machine, however, we are able to automate the fabrication process reducing the possibility of human error. In addition, the CNC machine allows us to fabricate the microtable in approximately 6 min, justifying the moderate expense (approximately $15,000). Obviated is the need for either an IGS system (approximately $100,000), as required by the NexFrame, or an accurate rapid prototyping machine (approximately $50,000), as required by the Starfix.

We have gathered clinical data, albeit limited, that shows a turn-around time—from CT scanning after fiducial markers are placed until complete assembly of a microtable—of under 45 min. This total time includes automated localization of the fiducial markers in the CT scan [14], automated planning of the surgical trajectory [17], generation of a virtual model of the microtable, translation of the virtual model to the CNC's input language, fabrication of the tabletop, quality assurance, attachment to the tabletop of legs with grippers used to fix the tabletop to the spherical fiducial markers, and labeling of the entire assembly to provide orientation. Anticipating 10–15 min of sterilization time, we conservatively estimate that a microtable can be made in less than 1 h.

We have performed eleven clinical validation procedures using the microtable (Fig. 10). All have been clinically successful [18]. We undertook the study herein to accurately document the upper limit of accuracy that can be clinically achieved using the microtable, which is submillimetric. While clinically intended for percutaneous cochlear implant surgery, other potential applications would include placement of deep brain stimulators and targeting tissue for biopsy purposes.

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