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Accuracy and Safety of Customized Stereotactic Fixtures for Stereoelectroencephalography in Pediatric Patients

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Stereoelectroencephalography · Drug-resistant epilepsy · Frameless stereotaxy · Localization errors · Stereotactic neurosurgery

Abstract
Stereoelectroencephalography (SEEG) in children with intractable epilepsy presents particular challenges. Their thin and partially ossified cranium, specifically in the temporal area, is prone to fracture while attaching stereotactic systems to the head or stabilizing the head in robot's field of action. Postponing SEEG in this special population of patients can have serious consequences, reducing their chances of becoming seizure-free and impacting their social and cognitive development. This study demonstrates the safety and accuracy offered by a frameless personalized 3D printed stereotactic implantation system for SEEG investigations in children under 4 years of age. SEEG was carried out in a 3-year-old patient with drug-resistant focal epilepsy, based on a right temporal-perisylvian epileptogenic zone hypothesis. Fifteen intracerebral electrodes were placed using a StarFix patient-customized stereotactic fixture. The median lateral entry point localization error of the electrodes was 0.90 mm, median lateral target point localization error was 1.86 mm, median target depth error was 0.83 mm, and median target point localization error was 1.96 mm. There were no perioperative complications. SEEG data led to a tailored right temporal-insular-opercular resection, with resulting seizure freedom (Engel IA). In conclusion, patient-customized stereotactic fixtures are a safe and accurate option for SEEG exploration in young children.

Introduction

Patients with epilepsy have a 30% chance of developing drug resistance [1, 2]. With the advent of epilepsy surgery, major strides have been made in the last decades to address this problem [3–5]. However, the presurgical workup necessary to assess the eligibility of patients and to optimally plan the resection is a lengthy and costly process, not devoid of risks [6, 7].

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One of the steps in the presurgical evaluation, reserved only for a selected subpopulation of drug-resistant epilepsy patients, is stereoelectroencephalography (SEEG) procedure. This method involves the stereotactic placement of intracerebral electrodes in the relevant cortical structures for delineating the epileptogenic zone (EZ) and mapping the eloquent cortex, the end goal being the definition of a resection plan that offers the highest chance of seizure freedom with the lowest chance of postoperative deficit. SEEG requires an experienced multidisciplinary team in order to be carried out successfully and safely.

Electrode placement accuracy is required for reaching the intended targets, as well as avoiding anatomical and vascular conflicts. The accuracy of the procedure was estimated by the difference between the planned entry and target coordinates and the accomplished ones [8–10]. A high accuracy reduces the chances of intracranial bleeding and ensures the correct exploration of cortical tissue, in line with the hypothesis of the EZ [6, 9–12]. There are a multitude of stereotactic systems that can be adopted for aligning the tool holder to the planned trajectory, using a frame-specific hardware or a handheld or robotic arm under frame-based or frameless conditions [9, 13–15].

The founders of the method, Talairach and Bancaud, used a frame-based method [16]. Updated to modern standards, this method implies a multistep preimplantation process with trajectory planning, affixing of the stereotactic frame to the patient's head, subsequent imaging and co-registration, and calculation of frame-based coordinates [17]. While apparently no less safe than alternate methods [15, 18], the possibility of human error is larger and the operating room (OR) time under anesthesia is increased. Additionally, the use of the rather heavy traditional frames in children, who have a relatively thin cranium [19], adds a further risk of skull fracture and pin penetration.

Robot-assisted SEEG Rosa (Medtech, Montpellier, France) and Neuromate (Renishaw Inc., Wotton-under-Edge, UK) present high accuracy and low OR times. However, a significant amount of pressure is still required to be applied to the skull through pins of stereotactic head fixation devices or Mayfield clamps to immobilize the patient in the field of operation of the robot [20, 21]. Some frameless systems attempt to maintain the advantages of robot-assisted systems, achieving comparable accuracy, operating time, and safety in children, while reducing the pressure applied to the patient's skull and minimizing the OR footprint of the system.

Here, we focus on the StarFix microTargeting Platform (FHC Inc., Bowdoin, ME, USA), which is a lightweight, patient-customized, 3D printed stereotactic fixture that has been recently demonstrated to be effective in SEEG procedures [9, 22, 23]. It is a lightweight fixture (typ. <300 g) that scales to the patient's anatomy and attaches with small threaded anchors without applying significant pressure to the skull. It incorporates guides aligned with all electrode trajectories, simplifying the entire surgical workflow.

This article presents the case of an MRI-negative large temporal-perisylvian SEEG exploration in a 3-year old pediatric patient with a thin and partially ossified skull. The procedure was approached with orthogonal and oblique trajectories targeting the opercular-insular cortex.

Case Report

Case Presentation

Our patient is a 3-year-old girl who underwent presurgical evaluation for drug-resistant epilepsy in our center. Seizures started at 2 months of age, with a high seizure burden from onset. Despite numerous antiepileptic drug trials, no significant seizure control was obtained. The longest seizure-free period was 14 days. Neuropsychological evaluation showed an autistic spectrum disorder, with decreased social contact, some stereotypies, and lack of verbal acquisition. In terms of nonverbal development, she presented an estimated IQ of 50.

From a semiological point of view, her seizures had the following sequence: clinical onset with a scared facial expression, followed by vocalization and staring. Occasionally, the seizures evolved into a bilateral asymmetric tonic contraction (left limbs more than right), with repetitive blinking and oroalimentary automatisms. Seizure duration was usually under 1 min, with no discernible postictal deficits.

Initial interictal EEG recording showed epileptiform discharges mainly in the right temporal-occipital area (T8 and P8), which were superimposed on a slow background activity. Structural 3T MRI did not show any clear epileptogenic lesion (see online suppl. Fig. 1; see www.karger.com/doi/10.1159/000510063 for all online suppl. material).

Noninvasive Presurgical Workup

Long-term video-EEG recording managed to capture 2 habitual seizures, which showed a focal electric onset in the right posterior temporal area (T8 and P8). Interictal 18-fluorodeoxyglucose positron emission tomography-computed tomography (FDG PET-CT) revealed hypometabolic areas in the superior temporal gyrus, inferior insula, and posterior aspect of the right operculum, mainly the supramarginal gyrus (online suppl. Fig. 1).

While the information offered by seizure semiology, scalp EEG, and FDG PET-CT scan was concordant and pointed to the right temporal lobe and the ipsilateral insular-opercular area as the likely culprits, the absence of a lesion on brain MRI precluded the pos-

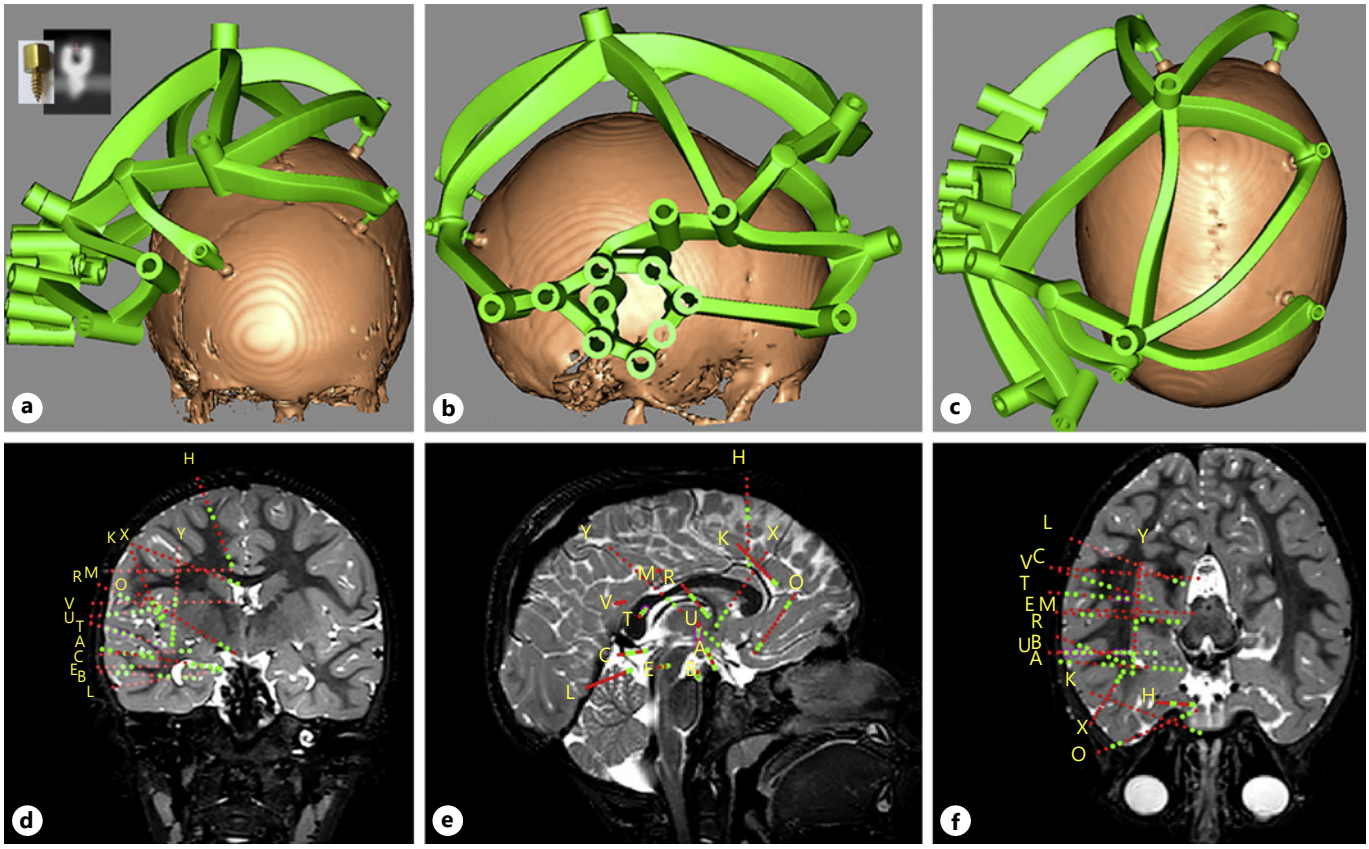

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Fig. 1. a–c Different views of the personalized stereotactic fixture used for implanting depth electrodes in the pediatric patient. The **inset** in panel **a** shows a 5-mm anchor and its appearance on the preimplantation CT. **d–f** Electrode localization, superimposed on patient's MRI. The contacts included in the recording montage ($n = 64$) are shown in green, while the remaining ones ($n = 131$) are shown in red.

sibility of a surgical resection based solely on this information. Therefore, we proceeded with SEEG invasive exploration based on a right temporal-perisylvian hypothesis.

SEEG – Implantation Procedure

Given the fact that the patient was 3 years old and had a very thin temporal bone, with an implantation plan focusing on the underlying region, we opted for the StarFix microTargeting Platform for the placement of electrodes. The first surgical step was the placement of 5 small bone anchors (4 mm or 5 mm threads) by making small incisions in the scalp (~5–10 mm) 2 weeks before electrodes' implantation [9, 22, 23]. The bone anchors were positioned around the implantation area, in places where the bone offered enough support. The anchors have a double role: (1) fixation points for the fixture and (2) fiducial markers.

The trajectory planning and the design of the customized, patient-specific fixture was carefully performed using Waypoint Planner surgical planning software (FHC Inc., Bowdoin, ME, USA) to reach the intended targets while going around anatomical and vascular constraints. A vascular safety index, characterizing the proximity of the planned trajectories to the blood vessels, was calculated for each trajectory [24]. A digital model of the fixture was generated by the planning software, shown in green in Figure 1a–c. The digital model was saved as a stereolithography file that was 3D printed at the manufacturer's production facility using selective laser sintering technology and shipped to our hospital for sterilization. The material used for printing is high-tensile PA12 medical-grade nylon, compatible with both ethylene oxide and autoclave sterilization. Using this technology and material, the printed stereotactic fixture was mechanically robust and weighed only 150 g. On the day of the surgery, the bone anchors were exposed and the fixture was attached to the patient's head in a matter of minutes using thumbscrews [9, 22].

A total of 15 SEEG electrodes (DIXI Medical, Chaudefontaine, France), having between 8 and 18 contacts to a total of 195 contacts, were implanted (Fig. 1d–f). A postimplantation CT was performed to check for the accuracy of electrode positioning and for possible complications (Fig. 2).

Implantation Accuracy

The implantation errors were characterized through the differences among planned and actual target and entry points of the electrodes [10]. Electrode locations were automatically detected

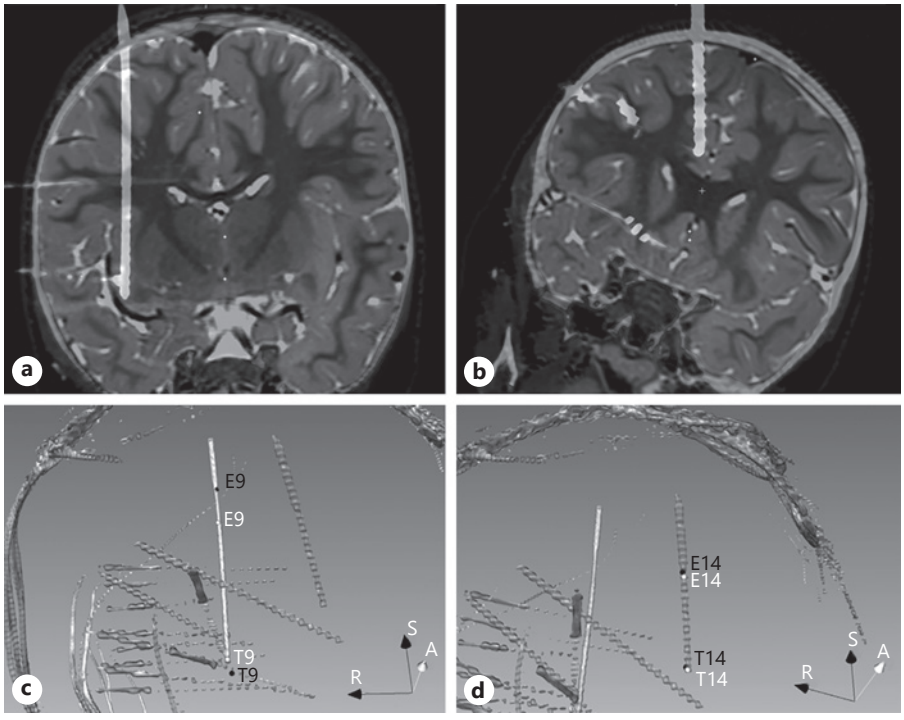

Fig. 2. a, **b** Two of the 15 electrodes targeting posterior insula and anterior cingulate implanted in our patient. **c**, **d** 3D view in slicer of the segmented postoperative CT showing the 2 specified trajectories, where the original (black) and automatically detected (white) entry and target locations are marked.

using the SEEG electroDE rEconstruction TOol (DEETO) software package [25] and verified visually. Error calculation was performed using MATLAB (MathWorks, Natick, MA, USA), and results were visualized using MATLAB and 3D Slicer software [9, 26].

Four types of localization errors were calculated in this study: lateral entry point localization error (LEPLE), lateral target point localization error (LTPLE), target point localization error (TPLE), and target depth error (TDE) (Fig. 3a). LEPLE and LTPLE represent the distance from the actual entry or target point to the planned trajectory axis, TPLE is the Euclidean distance between the planned target point and the electrode's tip, and TDE is defined as the difference between the planned target point and the electrode's tip projection on the electrode axis, as used in similar studies [8–10, 22].

Results

Accuracy of Electrode Positioning

All 15 electrodes reached their intended targets. There were no intracranial hemorrhages or other implantation-related complications.

The median localization errors were 0.90 mm (interquartile range [IQR] 0.54–1.20 mm) for the LEPLE, 1.86 mm (IQR 1.15–2.47 mm) for the LTPLE, 0.83 mm (IQR 0.27–2.21 mm) for TDE, and 1.96 mm (IQR 1.57–2.97 mm) for TPLE.

In order to be able to compare the localization errors among all 15 electrodes, we have aligned all planned trajectories with the *Z* axis of a 3D coordinate system, using geometrical transformations. The results of applying these transformations to the actual electrode locations are shown in Figure 3a, where the actual entry and target point locations relative to the planned trajectory are shown as gray spheres and black spheres, respectively. Time in the OR was represented by the average time per implanted electrode, which was about 7 min; this value is shorter than 21 min reported for past frame-based implantation procedures [27].

SEEG Recording and Resective Surgery

The patient underwent a 7-day monitoring session in our center, during which we managed to record multiple habitual seizures. She had no periprocedural adverse events and tolerated the implanted electrodes well. The seizures originated in the right temporal operculum (superior temporal gyrus), with rapid involvement of the posterior-inferior insula and, consequently, of the supramarginal gyrus and the mesial temporal structures (online suppl. Fig. 2).

Based on the SEEG recordings, the EZ, defined as the region of the beginning and of the primary organization of the ictal discharge [28], was delineated to include the

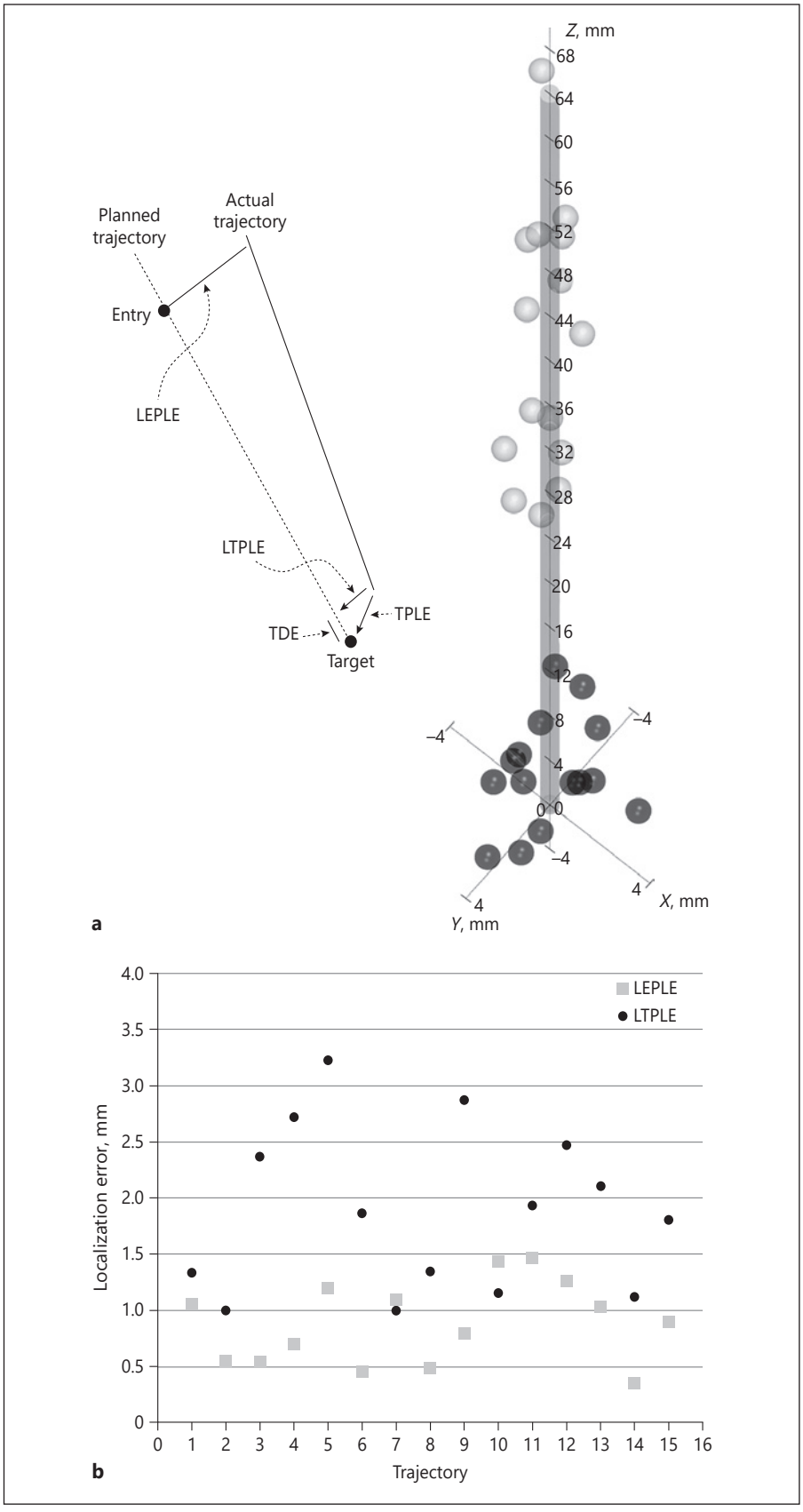

Fig. 3. a Representation of the method for calculating the targeting and entry point errors and the actual 3D localization of entry and target points for the 15 electrodes, relative to the planned trajectory. **b** LEPLE and LTPLE for each trajectory. LEPLE, lateral entry point localization error; LTPLE, lateral target point localization error.

anterior temporal lobe, the temporal mesial structures, the superior temporal gyrus, the supramarginal gyrus, and posterior insula. The patient underwent surgery, with the resection of the EZ as discussed in the multidisciplinary meeting, without any discernible neurological postoperative deficits. The histopathological analysis of the resected tissue showed a type IIA focal cortical dysplasia. At the 1-year follow-up, the patient was seizure free (Engel IA) [29].

Discussion

We found the StarFix microTargeting Platform to have several advantages over classical, frame-based systems for pediatric patients. With the traditional systems, one must attach a heavy metallic base frame to the patient's skull and reconfigure the frame for each electrode trajectory, based on a set of 5 Cartesian and angular coordinates [17]. When the number of electrodes to be implanted is in the range of 10–15, the possibility of human error increases and the total OR time is longer. Robotic systems address that issue, allowing a fast transition between trajectories; however, they still require the patient to be immobilized using pins that apply significant pressure to the skull, which is a particularly important issue for pediatric patients.

In contrast, the lightweight StarFix fixture scales to the patient's anatomy and has a small OR footprint, allowing for the patient to be positioned in an upright position. That facilitates access to all trajectories, including the ones requiring an occipital approach, which might be otherwise challenging for the robotic systems. With all trajectory guides included in its design, the transition between trajectories is fast, requiring a single depth measurement/setting per electrode. This greatly simplifies the implantation workflow. The accuracy of electrode positioning is comparable with the other methods [9, 10, 18, 30, 31].

The inability to perform intraoperative trajectory adjustments could be seen as a limitation, but we found it to be beneficial, as it forces a greater emphasis on the trajectory planning stage, when there are no stringent time constraints. What we also usually do is to plan additional backup trajectories in case an unexpected event prevents an electrode from being implanted.

The anchors are not removed until the end of the SEEG implantation, to allow repositioning of the electrodes following the postoperative CT scan, in case they have not reached their intended targets due to incorrect depth setting or excessive curvature. Reattaching the platform can be performed in a matter of minutes without any additional CT scan. From a cost perspective, for low-volume centers (less than about 15 patients per year), the high acquisition and maintenance costs of the robotic systems are offsetting the added per-procedure additional costs associated with the use of the StarFix stereotactic fixtures.

Many of the patients who undergo SEEG exploration have long-standing epilepsy [32], which is one of the variables associated with surgical failure. A possible reason why the presurgical workup is postponed in these patients is, among others, the fear of periprocedural complications, especially in the very young patients [15]. Since very young patients present a thinner cranium, there is an added risk of skull fracture, especially when using a general-purpose, rather heavy, metal frame [10, 33, 34]. However, according to the latest comprehensive reviews [6, 35], this complication has never been reported in SEEG procedures.

An early intervention could have a positive impact on the quality of life and social and cognitive development of children with drug-resistant epilepsy [36]. The StarFix fixture, with its lightweight design, high accuracy, and simplified OR workflow, could facilitate SEEG exploration in the pediatric patient subpopulation [36–38].

Conclusions

We found patient-customized stereotactic fixtures that scale to the patient's anatomy and apply minimal pressure to the skull to be a safe and accurate option for SEEG exploration in young children diagnosed with drug-resistant epilepsy.

Statement of Ethics

The informed consent was given by the parents of the patient to perform all clinical investigations and to use the collected data in research and publications.

Conflict of Interest Statement

Andrei Barborica is also a Chief Technical Officer and VP of FHC Inc., the manufacturer of the stereotactic platform used in this study. The other authors report no conflicts of interest concerning the materials or methods used in this study or the findings specified in this article.

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Author Contributions

Conception and design: I.M. and A.B. Acquisition of data: J.C., A.R., I.O., and A.D. Analysis and interpretation of data: C.P. Drafting the article: C.P. and A.D. Critically revising the article: A.B. and I.M.

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