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Force of cochlear implant electrode insertion performed by a robotic insertion tool: comparison of traditional versus Advance Off-Stylet techniques

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Abstract

Objective—Robotic cochlear implant electrode array insertion offers substantial potential advantages, namely repeatability and minimization of insertion forces leading to decreased intracochlear trauma. Using such a robotic insertion tool, we sought to analyze force profiles during deployment of stylet-containing electrode arrays using either traditional insertion, in which the stylet is withdrawn after complete insertion of the electrode, or Advance Off-Stylet (AOS) insertion, in which the stylet is withdrawn simultaneous with electrode array insertion.

Study design—Prospective.

Setting—Tertiary referral center.

Intervention(s)—A robotic cochlear implant insertion tool coupled with a force sensing carriage was used to perform electrode array insertions into an anatomically-correct, 3-dimensional scala tympani model during either straight insertion (n=4) or AOS insertion (n=4).

Main outcome measure(s)—Both insertion techniques begin with a 7mm straight insertion during which forces were similar averaging approximately 0.006N. For insertion from 7–17mm, traditional insertion forces averaged 0.046 ± 0.027 N with a peak of 0.093N and AOS insertion

forces averaged $0.008 \pm 0.006\text{N}$ with a peak of 0.034N . Beyond 9.74 mm , the difference between traditional and AOS insertion forces were highly significant.

Conclusions—With the use of a robotic insertion tool, which minimizes operator variability and maximizes repeatability, we have shown that cochlear implant electrode insertion via AOS is associated with lower average and maximum insertion forces, compared to traditional insertion. These findings support the use of AOS over traditional, straight insertion.

Introduction

Recent cochlear implant electrode designs have been aimed at decreasing intracochlear trauma, which is believed to lead to better preservation of residual hearing and improved post-operative audiological performance. One such electrode, the Freedom Advance electrode (Cochlear Corporation, Sydney, Australia), utilizes a stylet to keep the electrode straight during entry. When the stylet is withdrawn, the electrode assumes a pre-coiled shape to better conform to the quasi-helical geometry of the cochlea. When first introduced, the recommended technique was to completely insert the electrode following which the stylet would be withdrawn. This technique was then refined to the “Advance Off-Stylet (AOS)” technique in which, after insertion to a specified distance, the electrode is advanced while the stylet is held in place relative to the cochlea. AOS is designed to limit physical contact between the electrode array and the lateral wall of the cochlea, with the intent of decreasing the likelihood of intra-cochlear damage [10]. We sought to determine differences between AOS and traditional insertion by quantifying the force of insertion.

One of the difficulties in quantifying differences between insertion techniques is that human operators demonstrate a high degree of variability between trials. To maximize repeatability and minimize inter-trial variability, an automated insertion technique is necessary. Prior reports have demonstrated that automated cochlear implant electrode insertion with robotic devices is feasible [1, 2, 3, 4, 5, 6, 17]. Using such devices, the authors of these reports have analyzed the cochlear structure and behavior of different types of electrode arrays trying to find optimal insertion trajectories and velocities in terms of patient stress during and electrode position after insertion.

Simaan et. al. [1] used an insertion robot with integrated force sensing, offering four degrees of freedom (DOF), for their studies on insertion trajectories and velocity. However, their large, stationary device has been developed for experimental purposes and will require significant changes in design before it can be used in the operating room. Hussong et. al. [2–4] utilized a much smaller, portable robot with only one degree of freedom that could be introduced into the OR. However their initial design did not include integrate force sensing and required a stationary, external device to measure force during insertion. We modified the design of Hussong et al. to incorporate a forces sensing carriage that is integrated into the tool thus allowing intra-operative measurement independent of weight of insertion target (e.g. isolated temporal bone or whole head preparation) [6, 17]. Using this modified tool, we sought to quantify the differences in two common cochlear implant insertion techniques—AOS and traditional insertion—performing these insertions with micrometer precision and eliminating the confounding effects of human variability in experimental results.

Materials and Methods

The insertion tool of Hussong, et al.'s original design [2–4] with modifications by Schurzig et al. [6, 17] was used in the current study (Figure 1). Central to the original design is the use of two linear actuators (Model SL2060; SmarAct GmbH; Oldenburg, Germany) to which tools used to grasp specific portions of the electrode are attached. The first actuator and tool assembly is used to grasp the electrode array via a modified surgical alligator forceps (Model 180800FX; Fentex Medical, Inc.; Neuenhausen ob Eck, Germany). The second actuator and tool assembly is used to hold the stylet via a stainless steel hooked wire. While inserting, a tube with an outer diameter of 1.83mm at the front of the insertion mechanism guides the electrode array to the target and also supports the two tool assemblies (top left, Figure 1).

Coupled to the insertion tool is a force sensing carriage (top right, Figure 1). The carriage uses four flexible aluminum beams to transform the force along the axis of insertion into deformation which can be measured by four semiconductor strain gauges (Model SS-060-033-1000PB; Micron Instruments, Inc.; Simi Valley, CA). As such, the electrical readout of the strain gauges can be calibrated to reflect force of insertion. Furthermore, the carriage was designed such that the deformation and subsequent electrical readout from the strain gauges can be zeroed out prior to insertion experiments. Force resolution of 0.001N is achievable with this set-up.

An anatomically-correct, three-dimensional model of the scala tympani component of the cochlea (Med-el Corporation; Innsbruck, Austria) was used for experimentation. It was filled with soapy water to mimic intracochlear conditions. The insertion tool was loaded with a Freedom Advance cochlear implant electrode, and the tool positioned vertically above the model. This experimental setup is shown in Figure 2. Five insertions were performed each for straight insertion and AOS insertion. During these insertions, the force in the insertion direction resulting from the contact between electrode array and the scala tympani model was recorded with reference to the insertion depth in mm. The resulting force profiles were analyzed, calculating average and peak insertion forces, and compared using confidence intervals.

Results

In all 8 cases, the electrode array was successfully inserted 17mm deep into the scala tympani. Measured insertion forces are presented in Fig. 3 where individual experiments as well as averaged data are shown. Average force recorded during the first 7mm was $0.004\text{N} \pm 0.006\text{N}$ for AOS and $0.008\text{N} \pm 0.004\text{N}$ for straight insertion. Inside the spiral of the cochlea, during AOS deployment, average forces were $0.008\text{N} \pm 0.006\text{N}$ for AOS and $0.046\text{N} \pm 0.027\text{N}$ for straight insertion. Force maxima were 0.034N for AOS and 0.093N for the straight insertion.

As the first 7mm of both insertion techniques are the same, we calculated the 99.9% confidence interval (bias-corrected, bootstrapped) for the absolute value difference between

the 2 techniques. In Figure 4 we present this data noting that the difference between the insertion techniques exceeds the 99.9% confidence interval at an insertion depth of 9.74mm.

Discussion

Using a highly-reliable robotic insertion tool we have shown that AOS insertion is associated with significantly lower insertion force than traditional insertion in which the electrode is maximally advanced and the stylet withdrawn. It is a logical extension of this that less intracochlear trauma would occur especially considering that the rupture force of the basilar member in a human cadaver is 0.029–0.039 N [16] and that AOS forces routinely remained below this limit ($0.008 \pm 0.006\text{N}$) while traditional insertion forces exceeded it ($0.046 \pm 0.027\text{N}$). Thus AOS may allow better scala tympani placement, which has been associated with better audiological outcomes [11, 12, 13].

Our robotic insertion results are similar to prior work which compared different cochlear electrode insertion techniques (performed manually), as documented by Todd et al. [9]. Our data shows a statistically significant difference between the two techniques at an insertion depth of 9.74mm. While not statistically analyzed, Todd et al. noticed a qualitative divergence at approximately 8.5mm.

Also central to minimizing insertion forces, due to friction in between cochlea and electrode array, is correct alignment of the electrode tangent to the basal turn of the cochlea [14,15]. While this is easy to do in-vitro with a transparent model, in-vivo alignment of the electrode in the proper orientation is vital for avoiding contact with intra-cochlear anatomy, since such contact results in increased insertion forces and soft tissue trauma. One potential solution that our group is working on is using image guided surgical techniques to ensure optimal alignment of the electrode with the axis of the basal turn of the cochlea. We have reported on the use of microstereotactic frames to precisely target the scala tympani based on a patient's individual anatomy [7,8]. We are currently investigating the use of such microstereotactic frames to guide the robotic insertion tool in temporal bone specimens as shown in Figure 5.

Acknowledgments

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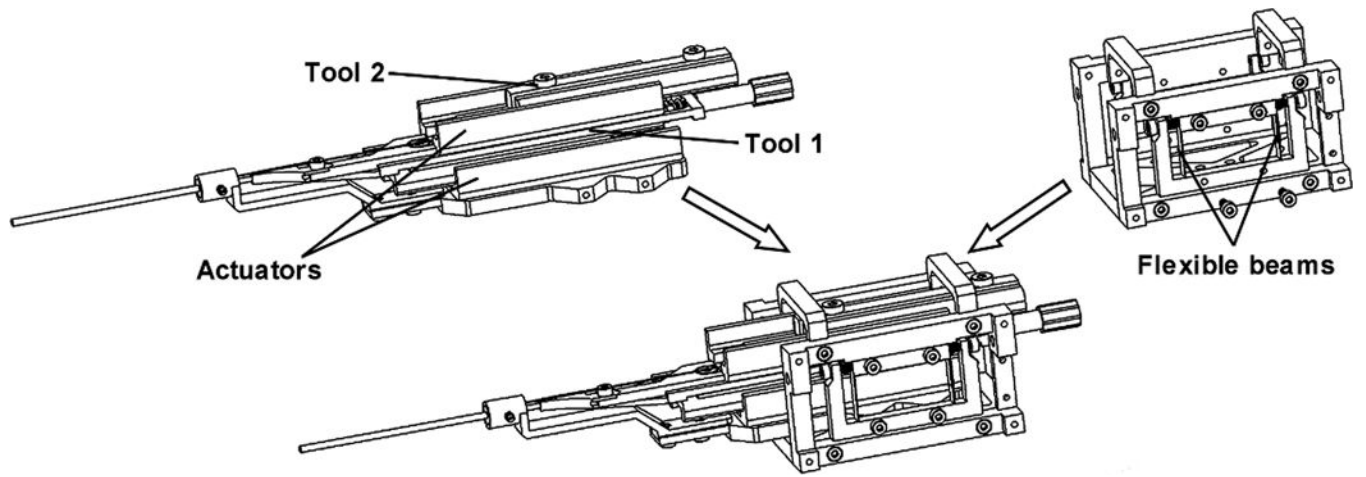


FIGURE 1. The insertion robot is composed of an insertion mechanism like described in [2, 3] (top left) and a force sensing unit (top right).

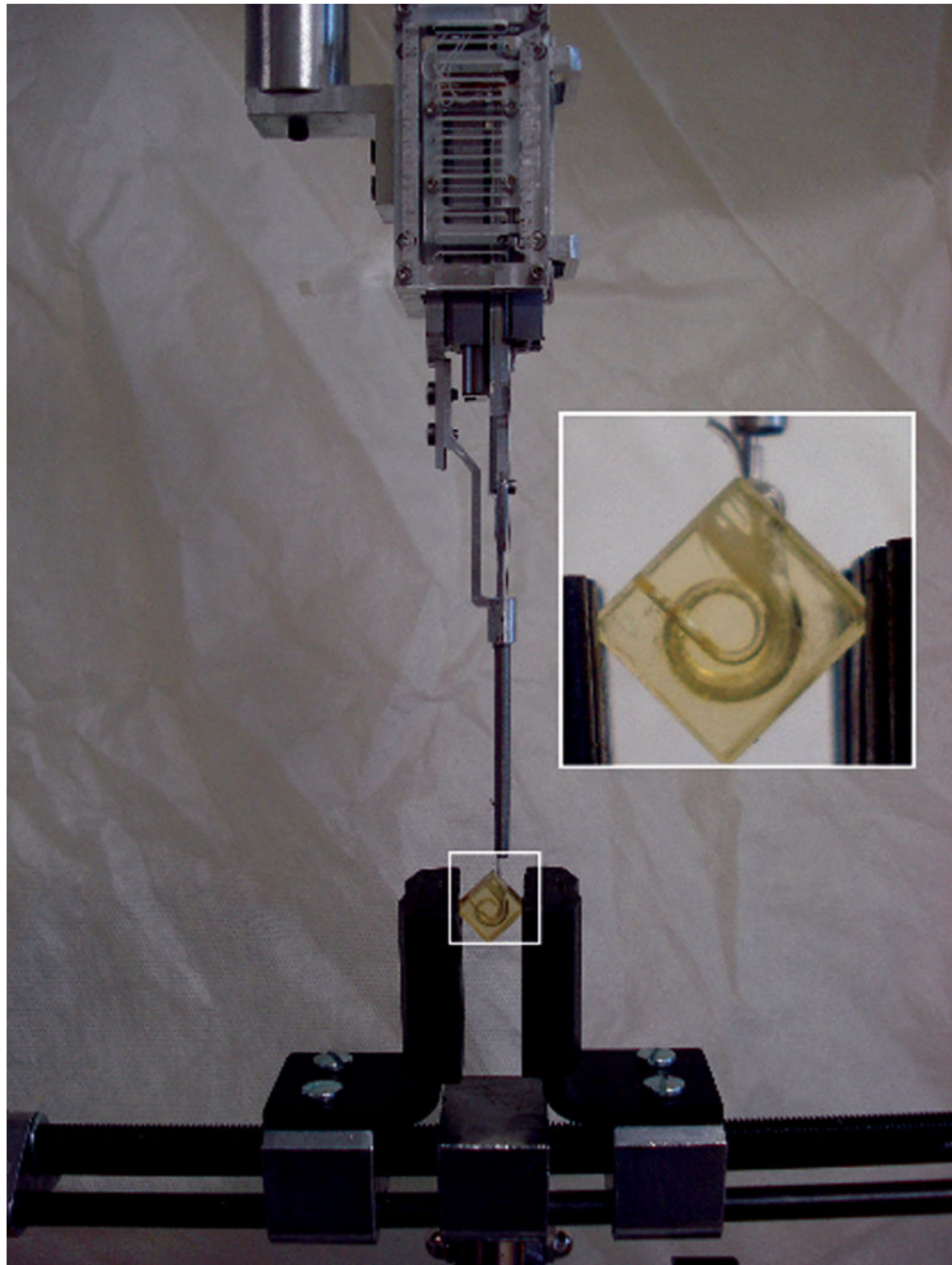


FIGURE 2.
The insertion robot positioned above the scala tympani model for electrode insertion experiments.

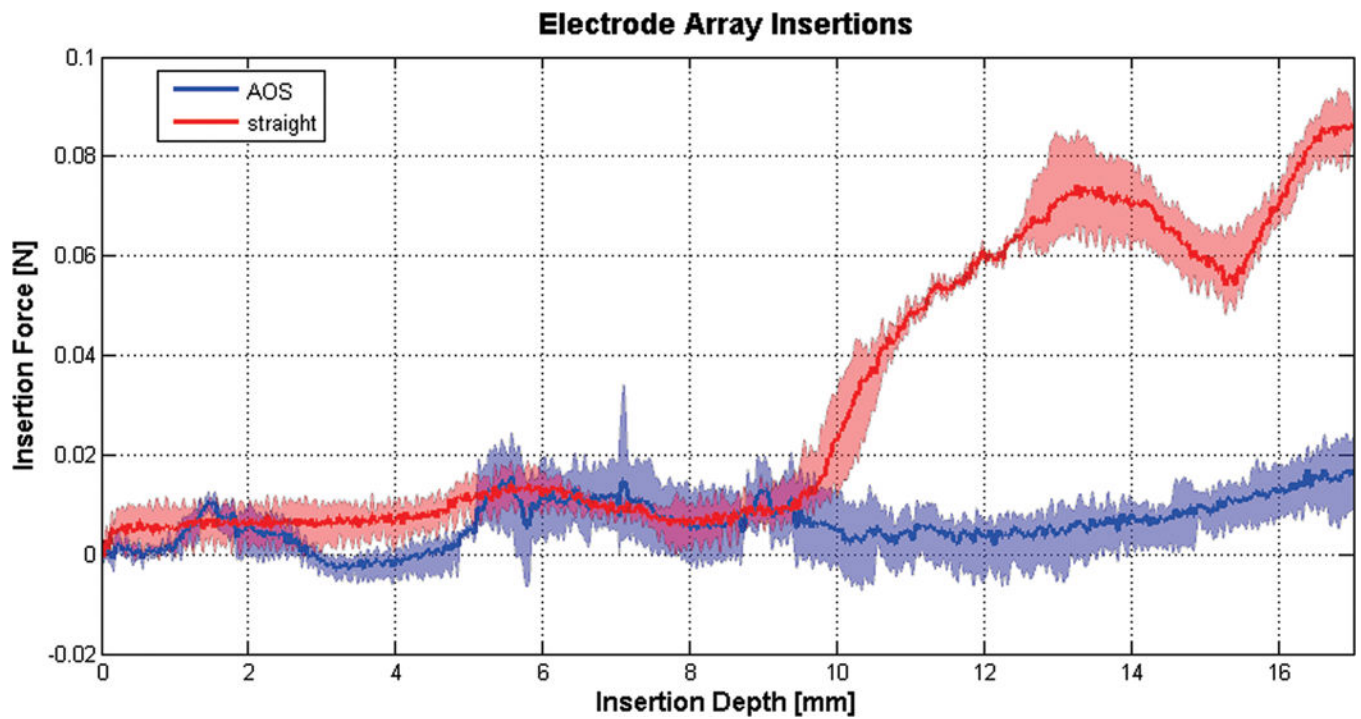


FIGURE 3.

Insertion forces recorded with the force sensing insertion tool. The solid red and blue lines represent the average force of AOS and straight insertion technique, and the shaded regions show the variability in insertion forces.

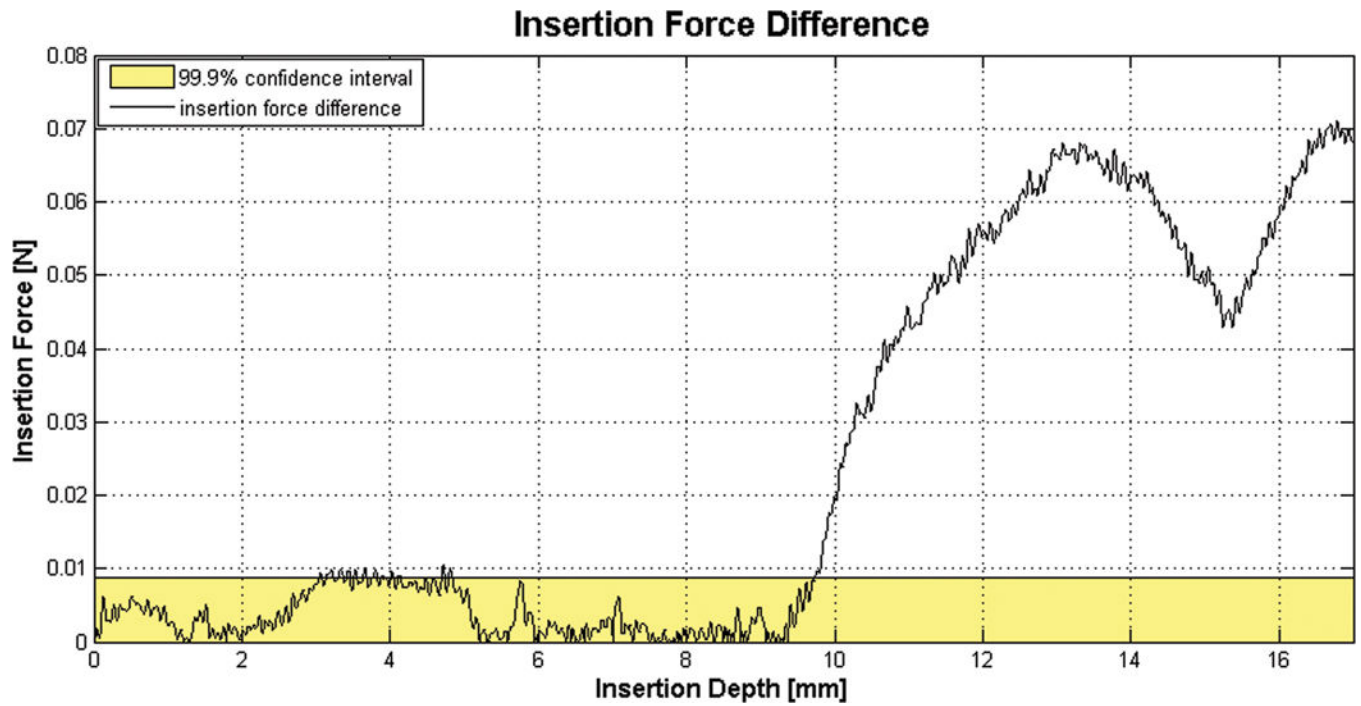


FIGURE 4.

Absolute difference of force between AOS and traditional insertion. The straight line at 0.0087N shows the 99.9% confidence interval of the first 7mm depth of insertion. Note that the force difference exceeds this interval at an insertion depth of 9.74mm.

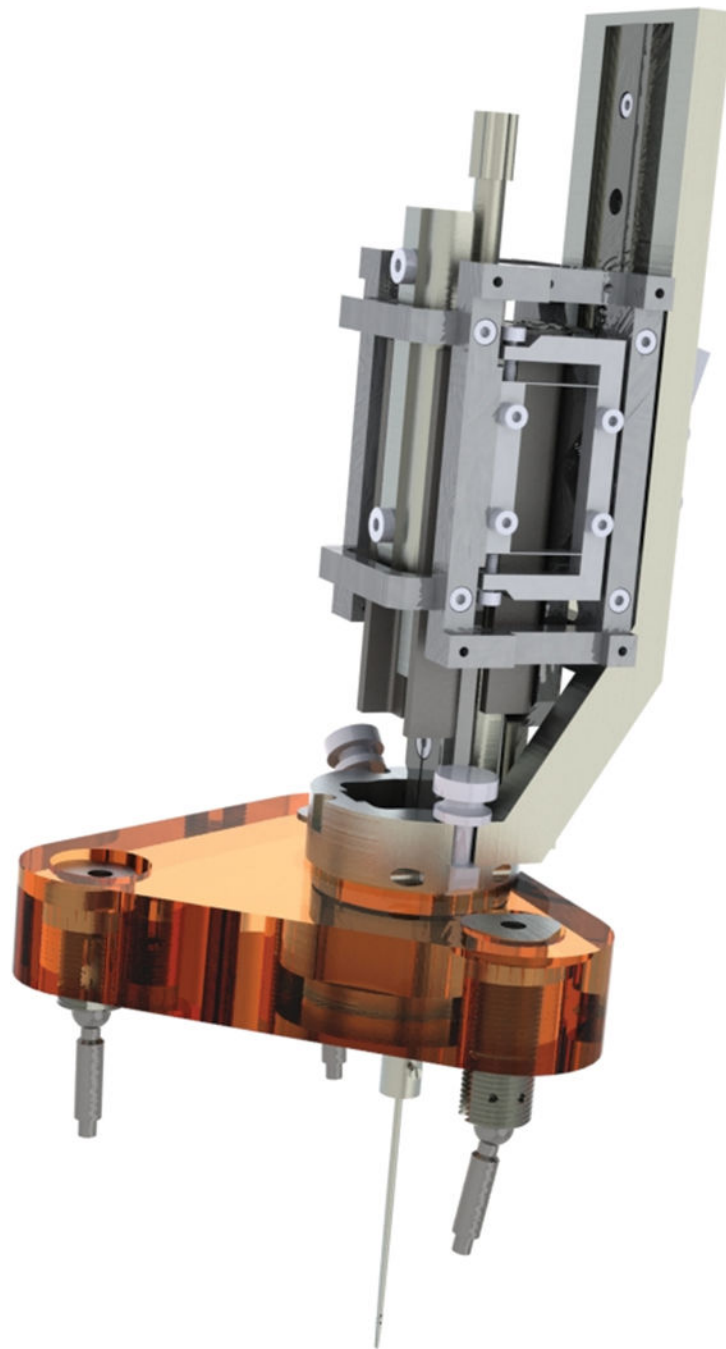


FIGURE 5.
CAD drawing of the Insertion Robot mounted onto the Microstereotactic Frame for optimal positioning relative to the target.