

# A Force Sensing Automated Insertion Tool for Cochlear Electrode Implantation

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**Abstract**—Cochlear electrode insertion is a challenging manual procedure. One technique requires the physician to coordinate the motions of an electrode array approximately 1mm in diameter and the smaller stylet within it, using miniature forceps. A new minimally invasive access technique precludes forceps insertion because the electrode must travel through a small-diameter drilled hole to reach the cochlear access point. To address this, we present an automated insertion tool. This second generation device not only enables deployment in the minimally invasive setting, but also makes insertion velocity profiles repeatable and can sense insertion forces. Force sensing is essential because insertion forces can indicate impending damage to cochlear membranes, but are below the thresholds that can be sensed by human hands. The Automated Insertion Tool we present is designed to be compact and lightweight for straightforward integration into the operating room environment. It is able to insert an electrode with a resolution of less than 1 $\mu$ m, achieve velocities of up to 5mm/sec and resolve forces as small as 0.005 N.

**Index Terms**—Cochlear Implants, Automated Insertion Tool, Force Sensor, Image-Guided Surgery

## I. INTRODUCTION

Cochlear implants restore hearing in patients whose mechanical-electrical sound transducers (hair cells in the cochlea) have failed. They do so by directly stimulating the nerves of the auditory system with electrical signals [7, 16, 18, 24, 25]. Modern cochlear implant systems have an external sound processing unit that transmits signals wirelessly to a receiver embedded under the skin of the patient behind the ear. The receiver is connected by a wire that travels through the bone of the skull to the cochlea in the inner ear and terminates in an electrode array (Fig. 1) that resides within the cochlea.

High quality sound perception by the patient requires that the electrode array be properly and deeply inserted into the cochlea, and that the delicate cochlear membranes be spared

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[9, 10, 22]. At our institution we use the Nucleus 24 Contour Advance Electrode (Cochlear Corporation, Inc.), which is a flexible precurved electrode that is straightened prior to deployment by an internal stylet. Deploying the electrode is extremely challenging manually, requiring advancing this 1mm diameter electrode array into a small hole in the cochlea. This must be done while working down a channel approximately 2mm wide at its narrowest point, in the traditional case where the surgeon mills out a pocket in the mastoid bone behind the ear. It is smaller still in the minimally invasive case, where only a single drill insertion is used to access the cochlea.

To accomplish insertion while “feeling” cochlear membranes during deployment – to preclude damaging them via excessive forces [23] – requires force sensing capabilities beyond the perceptual limits of the human hand. Furthermore, it has recently been shown that the frictional interaction between the electrode and the wall of the cochlea are dependent on insertion velocity [4], which leads naturally to the hypothesis that a repeatable and controllable insertion profile may produce less damage and better electrode placement than the current manual procedure.

Thus we have developed a force sensing automated insertion tool, motivated by the desires to 1) ensure safe

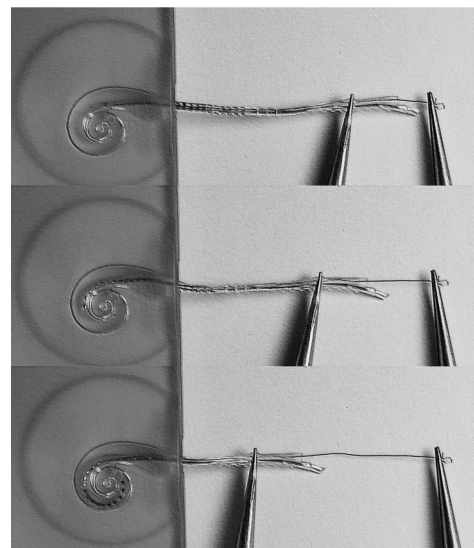


Fig. 1. Cochlear implant electrode insertion with the Nucleus 24 Contour Advance electrode involves simultaneously advancing the outer electrode while removing an inner stylet. Shown above is the Advance Off-Stylet technique for electrode insertion.

insertion via precise force sensing, 2) enable minimally invasive electrode deployment, and 3) provide a means of identifying optimal electrode deployment profiles (insertion velocity, force, etc., which need not be constant during insertion) and then accurately reproducing them.

## II. COCHLEAR IMPLANT ELECTRODE DEPLOYMENT

Optimal cochlear implant performance is achieved when the Contour Advance electrode array conforms to the helical shape of the cochlea. The precurved electrode array contains a thin straight metal wire – called a stylet – in a channel through its center to keep it straight. Pulling the stylet out allows the implant to return to its curled shape (Fig. 1). During insertion, electrode and stylet are advanced together up until the beginning of the first turn of the cochlea, at which time the surgeon holds the stylet fixed, deploying the curved silicone electrode array off of it. This “Advance Off-Stylet” (AOS) insertion technique is challenging due to the small size of the structures involved and the limited access to the surgical site. If the surgeon begins AOS too late, the array will not curl quickly enough, resulting in increased pressure on sensitive intracochlear structures and potentially incorrect final placement of the array (and a suboptimal hearing for the patient). On the other hand, if the surgeon begins too early, or retracts the stylet during insertion, the array can curl too quickly and fold over upon itself. Avoiding these complications and consistently placing the electrode arrays at its optimal position motivates the development of an automated insertion tool.

Several prior mechanisms have been proposed to achieve automated electrode array insertion. Simaan et al. [4, 21] use a single axis insertion robot with an attached axial force sensor in benchtop studies to analyze insertion friction. In prior work, some of the authors of this paper proposed a design involving two individually controlled linear actuators for performing automated insertions with programmable insertion profiles (including AOS) [6, 17]. This was a previous prototype of the automated insertion tool concept we present in this paper, but without force sensing.

Previous studies by the authors have involved placing a force sensor under a model cochlea to record insertion forces [1, 5, 12, 19]. While this is a reasonable approach for benchtop laboratory studies, transition to clinical practice depends on integrated force sensing. In this paper we present a number of mechanical and electrical design enhancements to the insertion tool of [6, 17], while

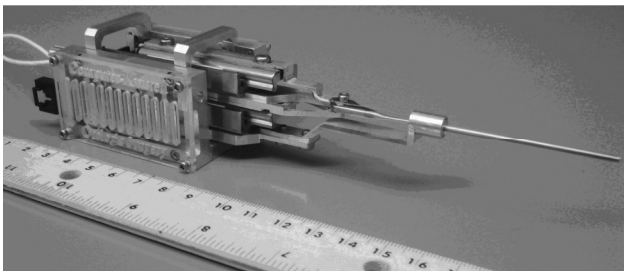


Fig. 2. Photograph of Force Sensing Cochlear Implant Insertion Tool.

integrating the tool-based force sensing concept of [4, 21]. Thus we contribute a second generation automated insertion tool with integrated force sensing, designed for straightforward integration into an image-guided positioning system used to align a drill for minimally invasive access to the cochlea, which is currently undergoing clinical trials [8, 11, 13, 14, 15].

## III. SYSTEM CONCEPT AND SPECIFICATIONS

To accomplish insertion using AOS or other techniques, we use one actuator to extend the electrode array and another to control the stylet linear position. Both of these actuators provide 1 degree of freedom (DOF) translational motion. The length of a cochlear implant electrode array is typically 30mm without, and 45mm with, the stylet. These dimensions are characteristic of the Nucleus 24 Contour Advance Electrode, which we used in initial studies. The length of the electrode prescribes the necessary travel of the actuators. Based on clinical guidance, a positioning accuracy of at least 0.01mm is desired. To determine the range of velocities the mechanism must be capable of, we observed experienced surgeons, and determined an average insertion time of approximately 10s. This implies an insertion velocity of approximately 3mm/s, so we designed our device to be capable of up to 5mm/sec. To deploy the electrode, mechanisms must be attached to each actuator to grip the electrode array and the stylet at the locations shown in Fig. 1 (though clinically the forceps are not perpendicular to the electrode shaft, but angled with respect to it to enable them to reach down into the opening in the skull). To enable minimally invasive deployment, the tip of the Automated Insertion Tool which contains the grip mechanism must be less than 2mm in diameter.

Our tool must also contain integrated force sensing capability. Preliminary experiments where the force sensor was mounted beneath cadaver temporal bones indicate that forces from 0-0.05N are relevant and a resolution of 0.005N is needed. These specifications are drawn from extensive experiments with experienced surgeons [1, 12]. Experiments and qualitative evaluation by an experienced surgeon indicate that a maximum deflection of the entire mechanism of 0.5mm is acceptable for force sensing without hindering electrode deployment.

Based on these specifications, our Automated Insertion Tool (Fig. 2) consists of two main modules, the Insertion Mechanism (Fig. 3) and the Force Sensing Unit (Fig. 5). The following two sections describe the design of these modules.

## IV. INSERTION MECHANISM DESIGN

An image of the Automated Insertion Tool we designed can be seen in Fig. 2, and an exploded view of the insertion mechanism is shown in Fig. 3. The Base and Front Plates

support the mechanism, and the electrode is delivered through the Guide Tube. The tube is connected via the Front Plate to the Base Plate which supports the actuators and gripping mechanisms. The Guide Tube has an inside diameter of 1.6mm and an outside diameter of 1.83mm, is 60mm long, and is slotted to enable the wire connecting the electrode array to the receiver to pass out of it. Within the guide tube are the Implant Gripper (Sec. IV-B) and Stylet Hook (Sec. IV-C), and the tip of the Guide Tube delivers the electrode array to the cochlea entry point. The connection point between the Base Plate and the Force Sensing Unit (Sec. IV-D) is via four M2 screws which thread into the triangular protrusions on the sides of the Base Plate.

#### A. Actuators

The mechanism specifications described in Sec. III require small and high-precision linear actuators. Based on these considerations, we selected the SL-2060 piezoelectric stick-slip linear actuators from SmarAct GmbH (Oldenburg, Germany). These actuators provide micrometer displacement resolution over 45mm of travel in a package 60mm x 20mm x 10mm, and so meet or exceed all specifications of our Automated Insertion Tool.

#### B. Implant Gripper

The Implant Gripper consists of modified surgical forceps model 180800FX from Fentex Medical, Inc. (Neuenhausen ob Eck, Germany). These forceps were selected because of their small diameter, which enables them to fit within a small guide tube. Additional advantages of using modified off-the-shelf surgical forceps are their high grip force and stiffness (in comparison to diameter).

Note that the gripper is able to open far enough to release the implant even when fully retracted within the Guide Tube. The shaft thickness of the forceps is 2.43mm at its base and tapers to 1.3mm at its tip. To facilitate loading of the electrode array, the forceps were cut to length such that their jaws extend 5mm beyond the tip of the Guide Tube when fully advanced.

To enable easy actuation of the forceps in a compact package, the finger loops were removed in favor of an adjustment screw mounted on the rear of the device as

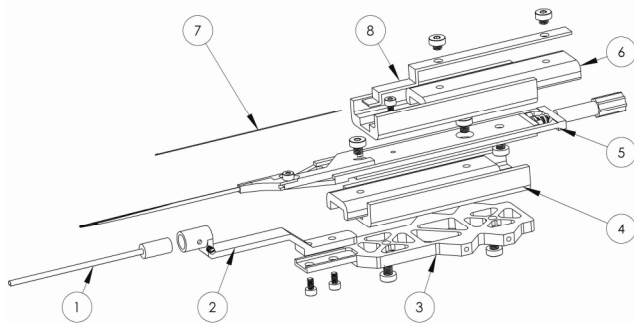


Fig. 3. Exploded view of the Robotic Insertion Mechanism showing (1) the Guide Tube, (2) the Front Plate, (3) the Base Plate, (4) Implant Gripper actuator, (5) the Implant Gripper, (6) the Stylet Hook actuator, (7) the Stylet Hook, and (8) the Gripper.

shown in Fig. 4. This screw was designed to be non-backdrivable, so that the forceps will not lose their grip if the physician removes his or her hand from the knob that actuates the adjustment screw. The slide is gripped between a shoulder on the screw and the spring, as shown in Fig. 4, and it adjusts the position of the slide relative to the middle plate, which actuates the forceps (Detail B on Fig. 4).

#### C. Stylet Hook

Since it is useful to have independent control of the electrode array and the stylet that straightens it, the insertion tool controls withdrawal of the stylet by means of a Stylet Hook. This hook extends along the Guide Tube in parallel with the shaft of the Implant Gripper forceps described above. Whereas the Implant Gripper is mounted on the bottom linear actuator (see Fig. 3), the Stylet Hook is mounted to the top linear actuator. The Stylet Hook is a 0.23mm diameter stainless steel wire with a hook at one end. A hook was selected to manipulate the stylet because its shaft can be very thin, and space within the Guide Tube is at a premium. Because relative motions between the stylet and electrode array are typically desired, the Stylet Hook actuator was mounted on top of the Implant Gripper actuator, to enable it to control differential motions between the stylet and electrode array.

Since intraoperative visualization of the interior of the cochlea is currently impossible clinically, insertion forces are an important indicator of errors in positioning and potential damage to cochlear membranes. Since the forces involved in electrode array insertion are very small – typically between 0 and 50 $\mu$ N [1, 12] – it was not possible to find an off-the-shelf force sensor that met our design specifications and could be incorporated into our insertion tool design.

The problem with conventional force sensors offering a

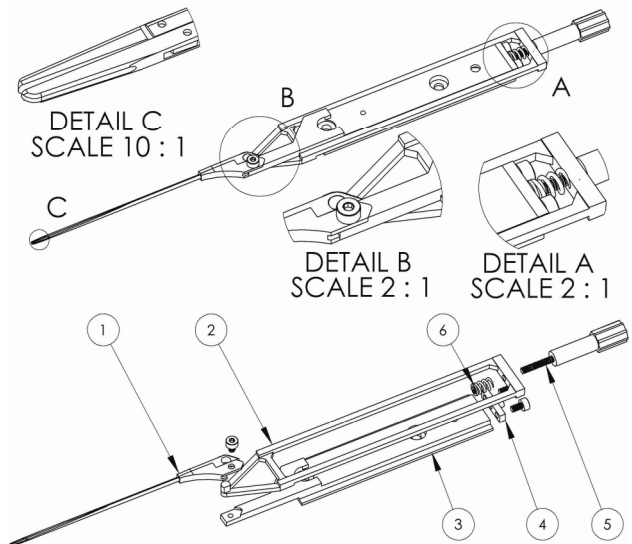


Fig. 4. Implant Gripper showing (1) forceps, (2) Slide, (3) Middle Plate, (4) Back Plate, (5) Adjustment Screw, and (6) spring.

high resolution like the LCL-113G from Omega Engineering, Inc. used in [1, 12] (which supported the model cochlea, not the insertion tool) is that they are typically not able to support significant loads, such as the weight of the entire insertion tool, without damage while making measurements. Since such off-the-shelf sensors use regular strain gauges, resistance changes result from diameter changes of electrical conductors. This implies that high sensitivity requires thin conductors that break if loads large relative to their measurement range are applied.

Thus, we chose to design a custom force sensing unit using semiconductor strain gauges rather than traditional strain gauges. Such strain gauges achieve sensitivities between 50 and 75 times that of traditional strain gauges, and are significantly more robust (they can generally bend significantly without breaking). The semiconductor strain gauges we chose were four SS-060-033-1000PB from Micron Instruments, Inc. (Simi Valley, CA).

Our custom force sensing unit measures the reaction forces between the Base Plate of the insertion tool and the “ground” to which the entire device is mounted (see Fig. 5 and 6). It consists of a collection of thin beams that convert insertion reaction forces into deformations large enough to be measured by strain gauges. This strategy allows us to design the structure and all dimensions of the force sensing unit precisely to the stiffness and force sensing specifications required in cochlear electrode insertion.

#### D. Basic Concept of Force Sensing Structure

We selected a force sensing structure based on thin beam flexible elements, as shown in Fig. 5. The flexible parts generating a measurable strain are the two vertical beams on each side which carry the whole Insertion Mechanism stably. Their dimensioning allows them to deflect primarily in the insertion direction and be relatively resistant to off-axis forces.

#### E. Dimensioning the Flexible Beams

The core units of the housing are the flexible structures shown in Fig. 6. Since there are two copies of this structure (one on each side of the Insertion Mechanism), the force

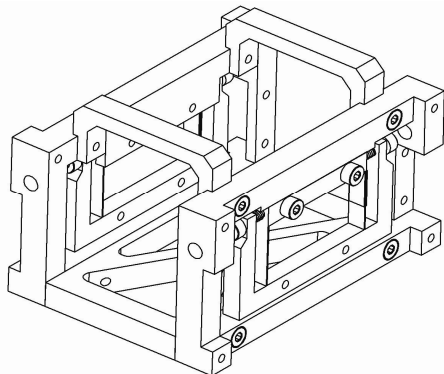


Fig. 5. Force sensing structure.

experienced by each is  $\frac{1}{2}$  the insertion force  $F$ . Since there are two vertical beams (with length  $\ell$ , height  $h$ , and width  $b$ ) on each side of the housing, the force is divided by two again, meaning that strain gauges will each provide measurements corresponding to  $F/4$ .

To increase their torsional and lateral stiffness as much as possible, the beams’ height ( $h$ ) is designed to be small compared to their width ( $b$ ). In order to limit maximum deflection ( $w$ ) mechanically, there are two limit screws per side, which set the maximum travel of the larger upright posts shown in Figs. 5 and 6. These are safety mechanisms to prevent over-stressing of the thin force sensing beams. Furthermore, if the limit screws are inserted completely, they make the structure rigid. While this is generally not desirable because it precludes force sensing, it is a useful capability to design into the mechanism in case some specialized future experiments do not require force sensing and to protect the force sensing mechanism during transportation and/or cleaning or sterilization procedures.

To dimension these force sensing structures, we use the maximum tool tip deflection specification discussed in Section III, namely  $w_{\max} = 0.5\text{mm}$ . Since the deflection is symmetric, this leads to  $w = 0.5 \cdot w_{\max} = 0.25\text{mm}$  for every “half beam” as shown in Fig. 6. To maximize device sensitivity, this deflection should occur when the maximum possible force is applied. This maximum force occurs when the tool is oriented vertically, so that the Guide Tube points downward with respect to gravity. In this configuration the entire mass of the mechanism  $m = 0.15\text{kg}$  is supported by the beams. Note that we neglect insertion forces in dimensioning beams because they are small relative to device weight. The force supported by each of the four beams is then  $F_B = m \cdot g / 4$ .

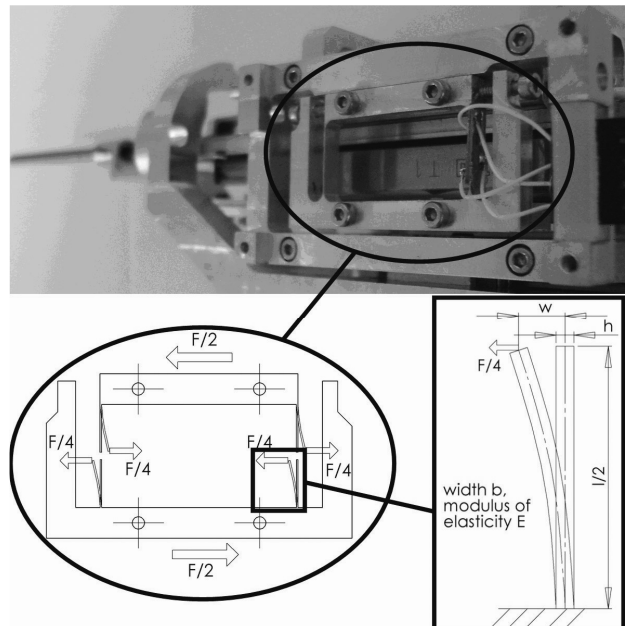


Fig. 6 The beams upon which the strain gauges are mounted deflect under load as shown in the diagram above, enabling force sensing.

Since the Micron Instruments semiconductor strain gauges have a width of approximately 3.3mm, the width of the beams was set slightly larger, to  $b = 3.5\text{mm}$ , to allow for gauge installation on the beam face. To keep the dimensions of the overall force sensing housing small, the beam length was set to  $\ell = 10\text{mm}$ . According to Bernoulli-Euler beam mechanics (see [2]), the deflection of a beam under tip loading is

$$w = \frac{F_B \cdot \left(\frac{\ell}{2}\right)^3}{3 \cdot E_{\text{Al}} \cdot I}, \quad (1)$$

where  $E_{\text{Al}}$  denotes the elastic modulus of 6061 Aluminum alloy (70GPa), and  $I$  is the cross sectional inertia of the beam. Using the  $b$  selected above and (1), along with the formula for cross sectional inertia of a rectangular beam ( $I = bh^3/12$ ), one can calculate the required height ( $h$ ) of the beam as approximately 0.15mm. To add an additional safety factor against slightly higher forces than expected, the height of the beam in our prototype was set to 0.2mm. This leads to a deflection of 0.2mm under maximum load, allowing us to sense insertion forces even if they exceed the previously defined range.

#### F. Strain Gauge Circuitry

As previously mentioned, the force sensor is designed to have a resolution of 5mN while supporting the weight of the insertion mechanism. This requires high sensitivity from both strain gauges and circuitry. Thus, we use the SS-060-033-1000PB from Micron Instruments, Inc. (Simi Valley, CA), which is embedded in a silicon pad for easy installation. Since the strain gauges are thermally sensitive we connected them in a full Wheatstone Bridge configuration. In our prototype, two strain gauges are attached via adhesive to each side of the beam described in Sec. IV-E above.

Since the Wheatstone Bridge will measure insertion forces together with a constant offset created by the weight of the Insertion Mechanism, the circuitry is designed so that an adjustable offset voltage can be subtracted from the output signal, before the amplified signal is transmitted to the A/D card (the DAS16/330 from Measurement Computing, Inc.).

To relate measured voltages to forces, it is necessary to calculate the gain of the Wheatstone Bridge circuit itself (after subtraction of the offset). This can be done by determining the intrinsic gain ( $G$ ) of the Wheatstone Bridge and flexible beam system [3]. Assuming all four strain gauges have identical nominal resistance  $R$ , this can be accomplished using,

$$\Delta V_{\text{out}} = \frac{\Delta R}{R} \cdot V_{\text{cc}} = G \cdot \varepsilon \cdot V_{\text{cc}} \quad (2)$$

where  $\varepsilon$  is the surface strain of the beam at the site of attachment of the strain gauge (which is 1/4 of the length of the beam from the fixation point in our implementation, as shown in Fig. 5). The surface strain of a beam as shown in Fig. 6 (see [2]) is given by

$$\varepsilon = \frac{3 \cdot \ell \cdot F}{8 \cdot b \cdot h^2 \cdot E_{\text{Al}}}. \quad (3)$$

Substituting (3) into (2), and using the beam dimensions from Sec. IV-E yields  $\Delta V_{\text{out}} = 0.87\text{V}$ . This signal is then amplified by a factor of 100 so that it approximately spans the A/D measurement range of  $\pm 10$  volts. Thus, output voltage is directly related to force applied.

## V. EXPERIMENTAL RESULTS

After assembling the tool, it was positioned vertically so that its tip points downward with respect to gravity. A procedure was then performed to calibrate the sensor and test its reliability. The first step of the calibration was to adjust the offset to account for the weight of the Insertion Mechanism. This was done by performing a voltage measurement without tool movement or applied tip forces, and adjusting the offset to zero the output signal. We note that this vertical configuration represents a worst-case scenario with respect to any possible nonlinear effects in our sensor. Thus, it is a good configuration from which to verify linearity in sensor output. We envision performing this offset subtraction during normal device use in the operating room in the future.

Next, to verify measurement accuracy and linearity, known weights were attached to the Insertion Mechanism while recording the force. Thus, both the system input (in N) and output (in V) of the sensor can be determined, and a constant voltage to force multiplication factor can be determined. This procedure was repeated 10 times with increasing and decreasing weight to test the sensor's reliability and hysteresis. The performance of the force sensor is shown in Fig. 7. The maximum deviation between

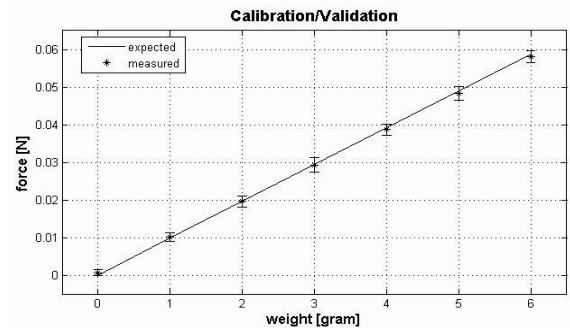


Fig. 7. The above plot shows the forces reported by the force sensor in comparison to the forces applied by hanging known weights from the insertion tool. The largest error across the measurement range was only 0.003N at a weight of 5 grams.

measured force and known applied force in the entire calibration range from 0 to 6grams (in steps of 1gram) is 0.003N. This value is within the desired resolution of 0.005N discussed in Sec. III.

## VI. CONCLUSIONS AND FUTURE WORK

In this paper we have described the design of a device for automated insertion of cochlear implants with force sensing. Automated devices such as the one presented have the potential to deliver cochlear implants with significantly more repeatable insertion profiles (force, velocity, displacement, etc.) than is possible with manual insertion. Furthermore the force sensing capability offered by our design can enhance safety by alerting the physician to incorrect placement and/or imminent damage to cochlear membranes. An automated device additionally enables a significantly larger range of insertion profiles than is manually possible and it is not yet known whether AOS or some other profile will be optimal. The tool we have described in this paper enables scientific study of candidate insertion profiles to quantify their characteristics in terms of forces, displacements and velocities. We foresee future studies carried out using our Automated Insertion Tool enabling enhanced models of cochlear electrode insertion and eventually improved cochlear electrode array placement, minimizing trauma to the cochlea.

While other methods of measurement are possible in benchtop experiments, force feedback is one of the few practical ways of intraoperatively sensing electrode-cochlea interaction effects, and hopefully identifying incorrect electrode insertions and/or impending damage to cochlear membranes. Thus, after addressing sterilization of the device (likely gas sterilization, although this is a topic of future investigation), the integrated force sensor in our design may enable translation of insertion strategies developed in benchtop ex vivo studies into clinical experiments. We anticipate that combined with future models of the forces generated in electrode placement, the force sensing capability of our insertion tool will be able to identify impending damage to the cochlea and adapt insertion profiles to avoid it, thus improving hearing outcomes for patients.

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