

Robot Assisted Stapedotomy *ex vivo* with an Active Handheld Instrument*

Tobia Vendrametto, Jacob S. McAfee, Barry E. Hirsch, Cameron N. Riviere, Giancarlo Ferrigno, and Elena De Momi

Abstract— Micron is a fully handheld active micromanipulator that helps to improve position accuracy and precision in microsurgery by cancelling hand tremor. This work describes adaptation, tuning, and testing of the Micron system for stapedotomy, a microsurgical procedure performed in the middle ear to restore hearing that requires accurate manipulation in narrow spaces. Two end-effectors, a handle, and a brace (or rest) were designed and prototyped. The control system was adapted for the new hardware. The system was tested *ex vivo* in stapedotomy procedure comparing manually-performed and Micron-assisted surgical tasks. Tremor amplitude was found to be reduced significantly. Further testing is needed in order to obtain statistically significant results regarding other parameters dealing with regularity of the fenestra shape.

Key words – medical robotics, tremor compensation, stapedotomy, handheld, micromanipulator.

I. INTRODUCTION

Otosclerosis is a hearing impairment due to abnormal and excessive bone growth. This interferes with the normal vibration of the middle ear ossicles, in particular the stapes, which is the final link in the transmission chain. Otosclerosis causes stapes fixation that restricts proper sound transmission to the inner ear, but it can be corrected by surgery [1].

Middle ear microsurgery is particularly challenging since surgeons manipulate human body parts about few hundred microns, and visualizing the surgical area through a microscope [2]. The surgery called stapedotomy [3], [4], consists in the replacement of the immobile stapes with a piston-prosthesis. After exposing the stapes, its superstructure is removed. Then a rosette (approximately circular shape made by overlapping laser bursts to weaken the bone and create an opening to house the prosthesis) on the stapes footplate is created, and a fenestra is opened. The rosette task requires high precision and accuracy and thus robotic assistance to stabilize hand motion, can be helpful. Subsequently, the piston-prosthesis is placed; it goes inside the fenestra and is secured to the incus. It replaces the

immobile stapes and the normal vibration of the middle ear ossicles is restored.

In surgery, the most common robotic systems are teleoperated robots in which there is a mechanically grounded robotic arm with multiple links and a console to control the robot. These systems have several advantages, like tremor filtering, motion scaling and remote control, but they are also complex, bulky, expensive, and completely change the traditional surgical workflow [5].

To overcome these drawbacks, a novel handheld robot called “Micron” was first proposed by Riviere *et al.* [6], in order to cancel hand tremor and enhance positioning accuracy during microsurgery. Handheld robots have the advantage of being inexpensive compared with other surgical robotic systems, and easily integrated in the conventional surgical workflow, since they are small and similar to a surgical instrument. They are intuitive to use, since they are handheld, and they have a safety advantage, because if the system fails, removal from the surgical field is easy and the surgery can be completed with conventional tools [5].

Micron is a fully handheld micromanipulator that aims to cancel hand tremor and achieve high positioning accuracy [7]. Its main components are:

- Micron handpiece (Fig. 1): it compensates hand tremor. Three piezoelectric motors deflect the tip in 3DOF with a motion equal but opposite to the hand tremor, so that compensation is accomplished.
- “ASAP” (Apparatus to Sense Accuracy of Position): its main components are two position-sensitive detectors and four infrared light-emitting diodes [8]. This apparatus detects the tool position in 6 DOF with a resolution of 4 μm at 2000 Hz.
- A real-time computer runs the control loop.

II. DESIGN METHODS

Micron was developed and adapted for middle ear surgery, taking as reference the demands of stapedotomy.

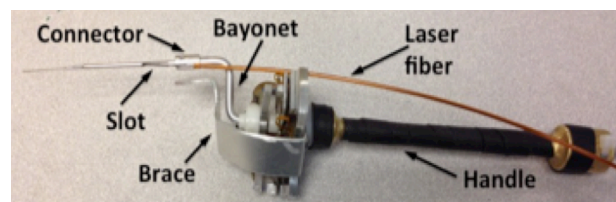


Fig. 1: Micron developed for middle-ear procedure: laser tool, brace and handle. The laser fiber comes from the laser machine and passes inside the laser probe through a slot, so the metal tip of the laser fiber is preserved.

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A. Ear Model

An artificial middle ear phantom was developed to test and assess dimensions and provide a working environment. It was made with dimensions according to [9]. The model incorporates an ear speculum, a plastic tube that resembles the ear canal, and a slip of thick paper on which a stapes footplate-like shape was printed (Fig. 2).

B. Laser probe

Starting from the OmniGuide, BeamPath OTO-S CO₂ laser fiber, a Micron-mountable laser probe was built, as seen in Fig. 1. It was made with a bayonet-shaped mount for an improved visualization of the middle ear, a connector made of aluminum, and the laser probe, which was a hollow stainless steel tube with a slot on the side for the fiber to pass through. Its high stiffness prevented vibration and its light weight resulted in low inertia, so it could be easily moved by the three piezoelectric stacks.

C. Brace and Handle

Two components were designed: a brace and handle (Fig. 1), for better compatibility with stapedotomy than the previous version [10].

The handle was fabricated using 3D printing. Brass was used because it is cheap and allows small wall thickness (min 0,5 mm) during the 3D-printing process.

The other component developed was a brace, rigidly fixed to Micron base. It was essential for two reasons:

- Protecting the tool moved by the stacks. If the tool touches something, motors saturate, and cancellation no longer works;
- Providing a resting point for the user: since the brace is rigidly fixed, the user can rest it against the speculum instead of resting the tool shaft. This allows stabilizing the hand and thus is a first tremor-reduction technique.

D. Control tuning

Micron control was tuned to obtain the best tremor cancellation with the new hardware. Micron has internal model control (IMC) (control block diagram can be seen in [7]), so a dynamic model of the manipulator with new tools was needed. A system identification process was implemented. A sweep sine signal (5-1000 Hz) was injected. The response of the Micron system was collected and analyzed in the frequency domain. A black-box model approach was used and state-space models were found, focusing on the 10-500 Hz frequency range, using 14 and 12

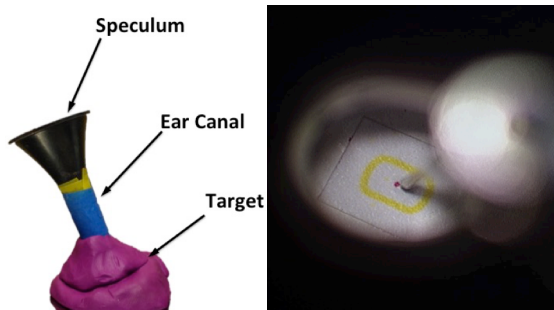


Fig. 2: Ear model (left) and view from the microscope (right).

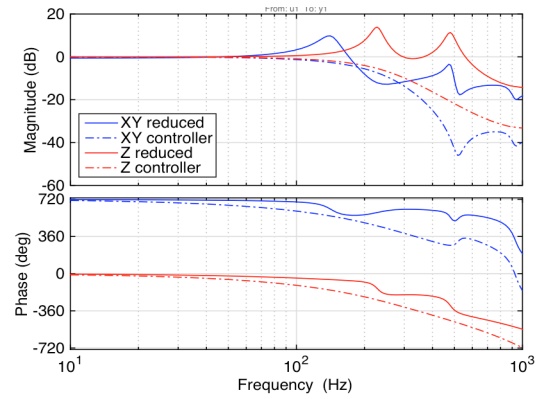


Fig. 3: Bode plot of the manipulator lateral (xy , blue) and axial (z , red) dynamic models. The system-filtered responses (dotted lines) are shown as well. This low-pass response suppresses the instability peaks, but adds lag.

states for the lateral (xy) and axial (z) motion respectively.

The number of states was a trade-off between best fit and complexity. Discarding the low Hankel singular values, an order reduction was achieved, with 8 and 6 states, respectively. Inverting the reduced model, keeping only the stable poles and adding two pairs of low-pass Bessel filter poles, the filter was obtained. The model multiplied by the filter gives the final dynamic response of the system.

Fig. 3 shows the dynamic models of lateral and axial motion of Micron tip. Instability peaks are present when the control is excluded (open loop). These resonances are smoothed by applying a filter: the responses considering the controller (close loop) are shown in dotted lines. A better control of the system is achieved at the price of adding lag.

The IMC system had a control bandwidth of 150 Hz, with a lag parameter of 7 samples. This information was obtained by injecting a step change into the Micron control and analyzing the time response in terms of overshoot and rise time.



Fig. 4: Experiment setup: 1) Micron; 2) Bone and holder; 3) Speculum; 4) Speculum holder; 5) ASAP; 6) Microscope; 7) Laser machine; 8) Hand rest.

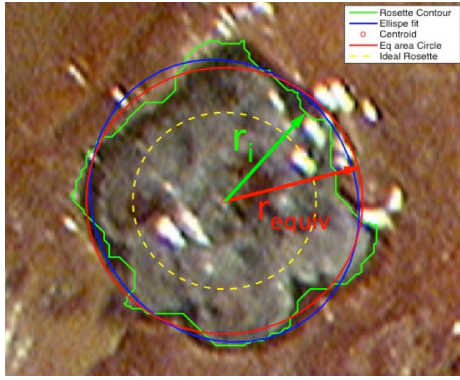


Fig. 5: Rosette contour detection. Contour (green), equivalent area circle (red) and best-fit ellipse (blue) are plotted.

III. EXPERIMENTAL METHODS

A. Experiment description

The rosette with subsequent fenestration and removal of footplate char are the most delicate steps of stapedotomy [11]. The aim of the experiments was to test if, with the help of Micron, tremor reduction and better rosette geometry could be obtained. Using Micron and the developed laser probe, the task was to perform the rosette.

Tests were carried out by two experienced otologic surgeons under a board-approved protocol, with robotic aid (*Micron on*) and unaided (*Micron off*). Five sessions were performed using the ear phantom. Subsequently, two sessions, using cadaver temporal bones, to test Micron in conditions closer to real surgery. The order of test conditions was varied to exclude order effects. For every session one aided and one unaided case were performed.

B. Experimental Setup

Fig. 4 shows the experimental setup. The surgeon held Micron, with the instrument inside the speculum. The laser probe was mounted on Micron, with the laser fiber coming from the laser machine, behind the surgeon. The speculum, fixed by a speculum holder (so a stable resting point was obtained) was inside the ear canal, giving access to the middle ear area. To magnify the working area a microscope (Leica Wild M650) was used with 16x or 25x magnification, according to surgeon's preference. To replicate surgical conditions, a hand rest was provided to simulate the patient's head. The ASAP was placed in front of the surgeon.

C. Performance measures and analysis

Excessive movement can lead to damage of middle ear structures. To quantify Micron performance, tremor characteristics and the regularity of the rosettes' shape were analyzed. Since the number of phantom and bone trials was small, all the data for the same variable were grouped together for analysis.

Analyzing the tip trajectory signal recorded during the rosette tasks, it was possible to estimate the tremor component by applying a band-pass ideal filter with bandwidth 6-12 Hz according to [12]. The tremor was characterized by two quantities: (i) RMS_{tremor} , RMS (root

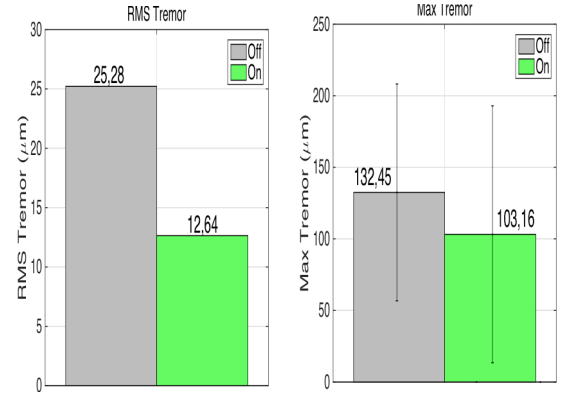


Fig. 6: Ensemble trials tremor data: RMS_{tremor} (left) and average Max_{tremor} (right). Error bars indicate standard deviation.

mean square) calculated on the concatenated tremor signals from all trials:

$$RMS_{tremor} = \sqrt{\sum_{i=1}^m d_i^2 / m} \quad (1)$$

where d_i is the 3D displacement due to tremor (Fig. 7) and m the total number of trajectory points; and (ii) Max_{tremor} , maximum 3D tip displacement (d_i) due to tremor during the rosette task, important in surgery because just one wrong motion can lead to important tissue damage.

To characterize the geometry of the rosette, it was necessary to detect its contour. A color-based segmentation method using K-means clustering was used to analyze the images from the microscope and detect the rosette contour [13]. Once the contour was detected, it was possible through MATLAB to compute the centroid, the best-fit ellipse, and the circle with equivalent area since the contour and the area were known, as seen in Fig. 5.

Two measures were chosen to characterize the rosette shape: (i) eccentricity e of the best-fit ellipse, indicating how circular the rosette was; (ii) $RMS_{contour}$, RMS of the distance between the rosette contour r_i and the equivalent-area circle r_{equiv} (Fig. 5), indicating how irregular the rosette contour was:

$$RMS_{contour} = \sqrt{\sum_{i=1}^n (r_i - r_{equiv})^2 / n} \quad (2)$$

where n is the total number of points in the contour.

Two non-parametric tests were used to determine statistical significance ($p < 0,05$): Kolmogorov-Smirnov (KS) two-sample test and Kruskal-Wallis (KW) test. Non-parametric tests were chosen because they do not rely on parameters estimated from the distribution, since the data population was small and the distribution unknown.

IV. RESULTS

A. Tremor

Fig. 6 shows the RMS_{tremor} and Max_{tremor} average during ensemble trials. The tremor reduction is noteworthy for both quantities: -50.0% and -22.1%, respectively. RMS_{tremor} is a single value computed on concatenated signals, so there is no standard deviation. For Max_{tremor} the KS and KW tests gave contrasting results in terms of p -value, but according to

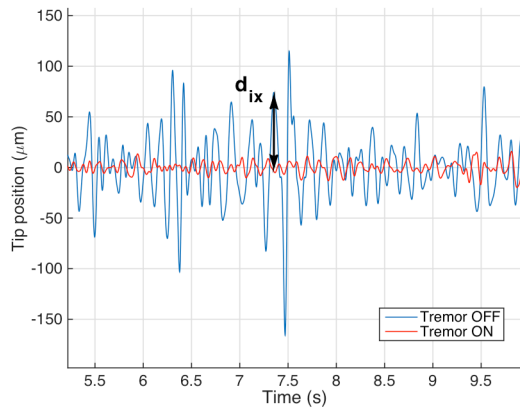


Fig. 7: Tremor cancellation effect: tremor amplitude in unaided case (blue) and aided case (red). To show Micron effect, 1D motion along the x-direction is shown, but the tremor is 3D, so x, y and z component were considered. The x displacement component d_{ix} is shown: this is the displacement from the zero-line to the tremor signal line.

the high standard deviation statistical significance seems dubious. Fig. 7 shows typical results in tremor cancellation.

B. Rosette geometry

Fig. 8 shows the mean across all trials of eccentricity e and $RMS_{contour}$ error with respect to a circle of equivalent area. It can be seen that e is slightly reduced in the aided case. The $RMS_{contour}$ decreases when Micron is on; however, the difference is less than 10 μm . Statistical significance was not reached in these cases.

V. DISCUSSION

In terms of tremor, Micron cancellation is effective, since RMS_{tremor} is reduced, resulting in a more controlled tip motion and reduced risk to hurt delicate middle ear tissues. Max_{tremor} , e and $RMS_{contour}$ are reduced, but these results are not confirmed by statistics. Nevertheless other factors affect the result when Micron is used, such as surgeon's fatigue, amount of training with Micron, and experience level. These factors need to be further investigated to assess their influence on outcomes, i.e., analyzing the learning curve.

Surgeons' opinion highlights the potential to control fine movements to minimize undesired excursions and the

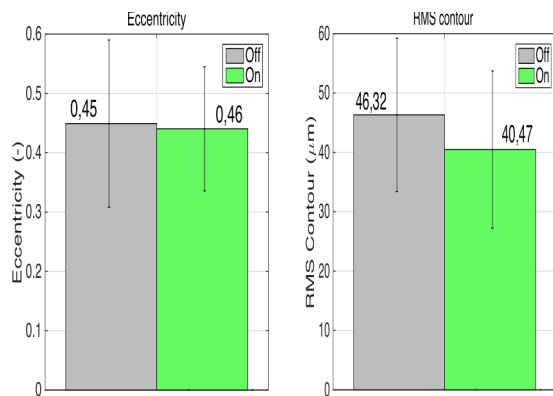


Fig. 8: Ensemble trials rosette geometrical data: average eccentricity (left) and average $RMS_{contour}$ (right). Error bars indicate standard deviation.

possible use of Micron in other surgical fields (e.g. ophthalmology). Complaints were the hindering of natural motion that sometimes happened due to saturation. To overcome this limitation the interaction between speculum, tool and motors need to be analyzed and improved in order to overcome saturation.

The results indicate that further experimentation is necessary in order to obtain significant results with regard to regularity of the rosette. Vision-based virtual fixtures [14] may be needed in order to improve laser targeting accuracy. Virtual fixtures could also enhance safety by preventing penetration of the vestibule during removal of char fragments from the fenestra after laser application.

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