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Instrument with multiple sensing channels for automated ventilation tube insertion on tympanic membrane☆

Wenchao Gao [a,b,*], Wenyu Liang [a], Kok Kiong Tan [a]

[a] Department of Electrical and Computer Engineering, National University of Singapore, Singapore
[b] NUS Graduate School for Integrative Sciences and Engineering, National University of Singapore, Singapore

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ABSTRACT

Otitis media with effusion (OME) is a common ear disease occurring in adults and children when the middle ear is infected, resulting in accumulation of fluid in the middle ear space and leading to complications. The current treatment is to surgically insert a ventilation tube into the tympanic membrane (TM) to bypass the Eustachian tube in draining fluid. An office-based robotic instrument allowing fast tube insertion has been designed in an earlier work of the authors. However, as the malleus bone is attached to the inner surface of the TM, this part of the membrane is to be avoided during the insertion process and the previous instrument relies on manual manipulation to locate the suitable insertion spot. In this paper, an instrument equipped with multiple sensing channels is developed to accomplish the procedure automatically. Leveraging on the machine vision and tactile sensing, the new instrument is able to manipulate the insertion channel to move effectively in the ear canal, without hitting the malleus bone to the desirable insertion spot accurately. A switching control mechanism is proposed to integrate the sensing channels and working stage. Pre-clinical tests on the harvested pig ears are carried out to verify the feasibility and efficacy of the proposed approach.

1. Introduction

Otitis media with effusion (OME), an accumulation of excessive fluid within the middle ear [1], is a common ear disease affecting children and adults worldwide. The ear of a patient with OME gets infected and conductive hearing loss may manifest when the vibration of the tympanic membrane (TM) and middle ear bones is affected. Besides, OME may cause body imbalance, discomfort in ear and irreversible damage to the middle ear structure as well [2]. To treat OME when medication fails, conventionally, a ventilation tube is surgically inserted on the TM so that the accumulated fluid can be drained [3].

This surgery is usually done in the operating room since general anesthesia (GA) is required. During the surgery, the patient's head is positioned along the line of view of the surgical microscope so that the surgeon is able to carry out myringotomy (i.e., making an incision into the TM using a surgical knife) under the visual guidance of microscopy. Then, a ventilation tube is carefully inserted through the incision using a forceps. So far, this approach is still predominantly used for OME surgery. However, like most surgeries operated in the operating room, the conventional surgical treatment for OME has the following limitations [4,5]: (1) the potential risks associated with GA, (2) the strict requirements of the surgeons' skills, (3) surgical trauma due to complications, (4) costly operating theater time, (5) lack of medical infrastructures in some poor areas, (6) treatment delay. To alleviate these disadvantages of the conventional surgical treatment, an office-based robotic instrument is a potential solution.

Over the past decades, a number of office-based instruments have been developed for ear diseases. In the literature, several studies in [4,6,9] have been reported laser-assisted myringotomy approaches to incise the TM under local anesthesia (LA). However, the conventional approach of manual tube insertion is still necessary. Besides, the needs for costly laser sources will reduce the cost-effectiveness of the instrument. Non-laser-based approaches have also been developed in [7,10–13]. But to the best of our knowledge, no sensing and control systems are constituent in those instruments. Consequently, there may be associated risks and uncertainties using those instruments within the constricted space in ear canal (the diameter of ear canal of is about 5–10 mm [14]) considering the vulnerability of TM.

To overcome the aforementioned drawbacks of the current art, a robotic instrument, allowing office-based tube insertion in an

☆ Fully documented templates are available in the elsarticle package on CTAN.

* Corresponding author. Tel.: +65 93756125.
E-mail address: gwc88@hotmail.com (W. Gao).

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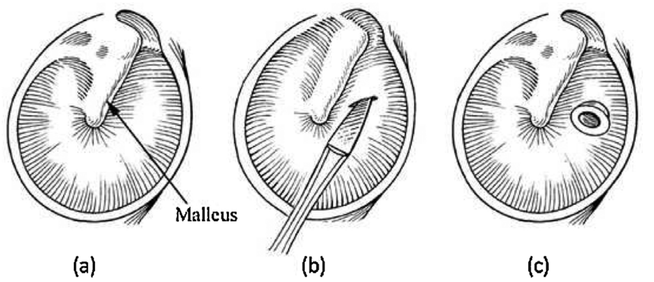

Fig. 1. Bone "Malleus" attached to the TM and desirable insertion spot: (a) shows the anatomy diagram of tympanic membrane, (b) shows the myringotomy on the tympanic membrane and (c) shows the grommet insertion at the desirable spot [17].

awake patient with chronic OME, has been developed in the previous papers [15,16]. The instrument can perform the tube insertion but it is unable to determine and locate the suitable insertion spot automatically. In fact, since the malleus bone is attached to the inner surface of TM, as shown in Fig. 1, to increase the success rate of tube insertion and minimise the surgical trauma, it is a critical requirement that the tube is inserted into the desirable spot on the TM without hitting the Malleus [17]. In addition, referring to the previous study [16], the instrument can achieve a better performance when the end effector (the tool's tip) has engaged the TM with a certain contact force before the insertion process is initiated. Therefore, the tactile status is a useful parameter for the instrument if an automatic working procedure is to be realized. Without feedback information from any external sensors, unless human intervention is called upon, the previous instrument is unable to function automatically.

In this paper, a novel surgical instrument involving machine vision and tactile sensing is proposed. The vision mechanism functions as the "eyes" of the surgeon to detect the suitable insertion spot on the TM, while the tactile sensor is introduced to enable the sense of touch to determine whether the TM is engaged by the tool set and to control the contact force. Machine vision and tactile sensing are two complementary sensing channels that can be exploited in a synergistic way to achieve the autonomy of a robot manipulator. With the feedback information, the visual perception of the surrounding environment together with the perception of the force applied to the end effector allows the instrument to adapt its motion trajectory to work within the confined environment in the ear canal, resulting a more effective instrument that can replace the surgeon to operate the surgery in an automatic way while significantly reducing the possibility of surgical trauma.

The control objective is to manipulate the tool set to engage the TM without hitting the Malleus by choosing a desirable track within the ear canal, to ensure that the contact force is within a certain tolerance and to insert the ventilation tube into the TM. To address the multitasking situation and facilitate the working procedure, a switching control scheme is proposed to integrate both sensing channels and coordinate the corresponding motion profiles efficiently.

The rest of this paper is organized as follows. First, the overview of instrument and the working procedure are provided in Section 2. In Section 3, the design of the control scheme is presented. The vision servo and the tactile sensing subsystems are described followed by the presentation of the switching control mechanism. Experiments and results are provided with the analyses and discussions in Section 4. Finally, conclusions are drawn in Section 5.

2. System overview

In this section, the mechanical design of the instrument and its working procedure will be presented in detail.

2.1. System design

The surgical instrument is designed as shown in Fig. 2. It mainly consists of the following components:

(i) A 2-degree-of-freedom (DOF) linear ultrasonic motor (USM) stage is designed to manipulate the tool set and ventilation tube in *X* and *Z*-axes. Both USMs are embedded with linear encoders manufactured by Physik Instrument (PI) to realize the precise motion control system requirement. The minimum incremental motion can be as small as 0.3 μm, while the travel range is 19 mm and the maximum velocity is 400 mm/s.

(ii) A linear stepper motor (STM) stage is used to manipulate the whole instrument up and down along *Y*-axis. For the STM, the resolution for each step is 1 mm, the travel range is 20 mm and the maximum velocity is 20 mm/s. The USM stage and the STM stage together form a 3-DOF monition system for the application. The *X*–*Y* plane is taken to be parallel to the surface of TM, and the *Z*-axis is along the axial direction of the tool which in aligned to the depth of the ear canal.

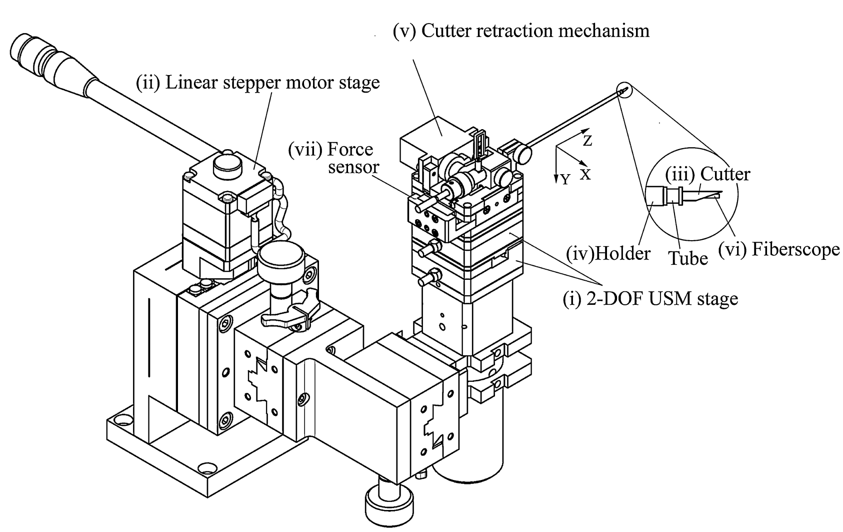

Fig. 2. Mechanical design of the surgical instrument.