ISA Transactions ∎ (∎∎∎∎) ∎∎∎–∎∎∎

Contents lists available at ScienceDirect

ISA Transactions

journal homepage: www.elsevier.com/locate/isatrans

Development of an intelligent surgical instrument for otitis media with effusion ☆

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ARTICLE INFO

Article history:
Received 12 January 2016
Received in revised form
31 July 2016
Accepted 2 September 2016
This paper was recommended for publication by Dr. Q.-G. Wang

Keywords:
Surgical instrument
Vision servoing
Fuzzy logical gain scheduling

ABSTRACT

To treat a worldwide common ear disease (OME), a device allowing fast grommet tube insertion has been designed in our earlier works (Gao et al., 2015 [1] and Liang et al., 2013 [2]). However, the instrument has to be manually placed as close as to the Tympanic Membrane before the insertion procedures. To realize a fully automated surgical process, the instrument shall be automatically manipulated to align to the axial direction of ear canal and proceed to complete the surgery. A vision-based servomechanism is proposed to solve the path planning problem. A fuzzy-gain-scheduled controller is proposed to minimize the projection error based on the image detection and the proximity measurement. The proposed controller is proven to outperform the traditional PI controller in pre-clinical trials.

1. Introduction

Otitis media with effusion (OME) arises when fluid accumulates in the middle ear space [3]. Conventional treatment for OME requires a professional surgeon to conduct a manual operation on the TM, where a ventilation grommet tube is surgically inserted into the membrane so that the accumulated fluid can be drained out [4]. During this surgery, the patient is put under general anesthesia (GA), the tube is then carefully inserted through an incision created on the TM by using a forceps. This method is still predominantly used in OME surgeries. However, several limitations associated with such method exist [5–7]: (1) the need for GA with associated risks; (2) highly dependent on surgeons skills; (3) costly operating theater time; (4) the patients in some areas with poor medical infrastructures are deprived of appropriate or prompt treatments; and (5) treatment may be delayed due to the waiting time for operating room and preparation of resources for the surgery.

In our earlier works [1,2], a robotic instrument has been developed to overcome the drawbacks of current arts. The core engine of the instrument is the motion controller and sensory feedback to achieve the high precision, fast response and repeatability necessary to allow tube insertion to be executed automatically. Nevertheless, the instrument functions properly only when the working channel is manually placed within a predefined starting position close to the TM. The automated motion profile of manipulating the instrument from outside the ear to the vicinity of tympanic membrane has not been addressed. To develop a fully automated surgical instrument, it is a crucial step to fix the mentioned path planning problem, so that the working channel can smoothly approach the suitable position where the subsequent insertion profiles can be performed. In this paper, we are concerned with the problem of 3*D* manipulation of a needle-shaped working channel approaching to TM, meanwhile, aligning to the central axis of External Auditory Meatus (EAM) of patient's ear (illustrated as the “desirable movement” in Fig. 1). The auditory meatus can be taken as a straight canal in this application. Therefore, to simplify the control process, the 3*D* manipulation will be handled separately in the form of X–Y vision servo and Z-axis switching control, and both control channels are executed simultaneously to reduce time consumption.

The distance measurement between the end-effector (tip of working channel) and EAM is the key feedback signal to control the motion path in Z direction. However, considering the constricted space of human ear, the proximity sensor (“red square”) mounted on the instrument can only provide less-than-perfect measuring performance due to the constraints of sensor size and installation difficulty. To fix this problem, a Kalman filter based sensor fusion method is introduced to improve the measurement accuracy through online states estimation. In addition to the

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http://dx.doi.org/10.1016/j.isatra.2016.09.005
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Please cite this article as: Gao W, et al. Development of an intelligent surgical instrument for otitis media with effusion. ISA Transactions (2016), http://dx.doi.org/10.1016/j.isatra.2016.09.005

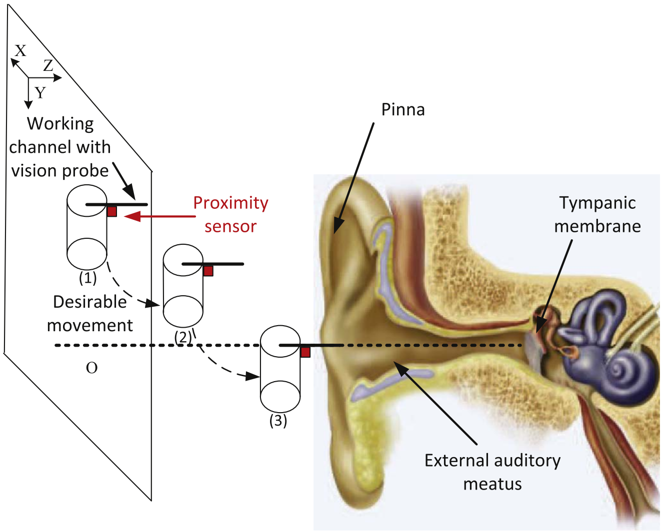

Fig. 1. Human ear anatomy with desirable instrument motion trajectory. Line "O" indicates the direction orientated to the depth of EAM. "O" is parallel to Z-axis which is perpendicular to the motion plane of X–Y. (For interpretation of the references to color in this figure caption, the reader is referred to the web version of this paper.)

proximity sensor, the size of the target object in the image space can be used to gauge the proximity as well. Hence, both channel g of measurements are imported into the fusion mechanism. Better than the single but noisy sensing output, the fused signal containing information from physical proximity sensing and image feature extraction significantly mitigates the effect of measurement noise and bias. The control strategy used is a straightforward on-off switching control according to the fused measurement. More specifically, the instrument will be manipulated in Z-axis towards EAM with a constant speed and only be stopped when a certain threshold proximity value is reached.

Because of the eye-in-hand design of our vision system (vision probe mounted through the working channel), locating the target in the center of the image is the goal of X–Y servo tracking. It is well recognized that visual servomechanism is an important tool for those surgical processes when the vision probe (fiberscope) functions as the "eye" of the surgeons in the traditional manual approaches [8–10]. In this application, an image based vision servoing (IBVS) system should be used, which does not require a three-dimensional object model [11].

Due to the geometric relationship between the vision probe and patient's ear as shown in Fig. 1. Detecting and tracking the target EAM via 2D image sequence becomes the first step. Leveraging on the fast image processing algorithm of a modified fuzzy c-means (FCM) clustering, the image view can be processed into clearly segmented groups, where the boundary of target region can be easily extracted and tracked. After feature detection and extraction from the robotic "eye", visual feedback information, namely, the projection error between the centroid of the target region and the image center can be exploited for the path planning on the X–Y plane.

A model predicted vision servoing method has been proposed in [12], where feedback visual features were combinations of moments extracted from the observed image. However, the prediction computation may affect the servoing speed, which significantly extends the surgery duration. Onal and Sitti [13] proposed an iterative sliding mode controller to precisely manipulate microparticles under a Nanoprobe, but only linear trajectories can be generated through this method. In addition, conventional PI/PID controllers have been widely used in case of 2D IBVS [14–16]. However, since the dynamics of the vision system even for a reduced mathematical model is time-variant and highly nonlinear in this application, the controller has to be designed with special care. In this paper, a fuzzy gain scheduled proportional and integral (FGSPI) controller is proposed to deal with the sophisticated scheme of path planning. Fuzzy logic has proven to be a suitable method of mapping input to output where non-linear relations can be realized in the literature [17–19]. In our proposed approach, the control parameters (gains) can be changed quickly based on the system inputs and mapping rules based on fuzzy reasoning. Instead of having fixed control parameters, the new controller is able to adapt efficiently with the changes in control environment when the fiberscope approaches the EAM, and achieve superior control performance along the 3D motion trajectory compared to the standard way.

The rest of this paper is organized as follows. Section 2 briefly introduces the mechanical design and configuration of the overall system. The FCM clustering image processing and object tracking method will be covered in Section 3. In Section 4, the methodology behind the fuzzy-rule based servomechanism will be elaborated. Section 5 presents the experimental setup and the results on a human ear model followed by the safety issues of the automated system in practical situations in Section 6. The final conclusions are drawn in Section 7.

2. System design and configuration

Shown as the human ear anatomy in Fig. 1, EAM is like a tube running from the outer ear (pinna) to the middle ear (TM). Although it usually has a sigmoid (nearly "s" shape), in conventional OME surgery the patient is in prone position with the head turned so that the operated ear is facing toward the surgeon, placing the ear canal on a straight line with the surgeon's view [20]. The effective way of developing an automated instrument is to mimic surgical procedures from human surgeon. Therefore, the working channel is initially taken to be parallel to the Z-axis, and will keep this orientation until it reaches the suitable location along the depth of the ear canal indicated by the dashed line "O".

The control objective is to align the working channel on the X–Y plane with line "O" and to control the instrument to move forward as close as possible to EAM. An example of desirable motion trajectory starting from an arbitrary position in space to the vicinity of TM is illustrated by the dotted arrow ((a)–(c)) in Fig. 1. In view of the mentioned mission, the mechanical design of proposed instrument is designed and shown in Fig. 2. It mainly consists of four components:

(i) A linear ultrasonic motorized (USM) stage is introduced to manipulate the tool set with 3 degree-of-freedom (DOF), in which motor "A", "B" and "C" can be controlled to move along X, Y and Z axes, respectively. Linear encoders are embedded inside the USM stage to provide positioning information to the controllers.

(ii) A proximity sensor attached closely under the working channel collects the distance data from the sensor to the target EAM. The measurement data minus the length of the needle provides the proximity from end-effector to the target position, which also contains the feedback control information as error signal.

(iii) A hollow cutter is designed for making incision on the TM and holding the tube which is located at end-effector.

(iv) A flexible fiberscope with small dimensions is mounted on the USM stage to provide visual guidance through the hollow holder on the working channel. This eye-in-hand vision probe has a precise sight of the scene and is able to obtain meaningful visual information of the target. Together with the tube cutter, the telescopic structure is adapted to integrate the functional components and minimize the size of the instrument due to the space

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