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Stabilization system on an office-based ear surgical device by force and vision feedback☆

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ABSTRACT

An "office-based surgical device" is a kind of device which aims to shift the conventional surgical procedures from the operating room to the confines of the doctor's/surgeon's office as well as to assist the surgeons to carry out the surgeries on the patients automatically or semi-automatically. In this paper, an office-based surgical device suitable for patients with Otitis Media with Effusion (OME) is introduced. Due to the office-based design, it is not possible to subject the patient to general anesthesia, i.e., the patient is awake during the surgical treatment with the device. To ensure a high success rate and safety, it is very important that the relative motion and the contact force between the tool set of the device and the tympanic membrane (TM) can be stabilized. To this end, a control scheme using force and vision feedback is proposed. The force feedback controller is a PID-based (proportional-integral-derivative) controller, which is designed for force tracking. The vision feedback controller is a vision-based motion compensator, which is designed to measure and compensate the head motion since it is equivalent to TM motion. Furthermore, the control scheme is implemented and tested in a mock-up system. The experimental results show that the proposed composite controller can achieve much better performance in force tracking than a pure force feedback controller. The performance can at least improve by 20% after augmenting the motion compensator, which helps the system to stabilize the relative motion indirectly and maintain the contact force precisely.

1. Introduction

In recent years, an increasing number of auto or semi-auto surgical devices and robots are used to assist surgeons in carrying out the surgeries. Many of them are designed to provide surgical treatments to patients automatically or semi-automatically in the doctor's/surgeon's office rather than the operating room. These devices are called "office-based surgical devices", which offer many advantages such as: (i) removing the need for the extensive and expensive resources of operating room settings including specialized equipments and surgical team; (ii) simplifying the surgical procedures and thus avoiding the high dependence on the surgeon's skills and (iii) improving the precision, speed and success rate for the surgery. Therefore, office-based surgical devices can greatly reduce the cost, waiting and operating time and thus it also increases the access to medical treatment for patients in areas with poor medical infrastructures.

Otitis Media with Effusion (OME) is a common ear disease affecting children and adults worldwide where there is a collection of excessive fluid within the middle ear (behind the Tympanic Membrane, TM) [1]. To treat OME after medicine fails, a ventilation tube (also known as "grommet") is surgically inserted on the TM (eardrum) so that the pressure between the middle ear space and the atmosphere can be balanced and the fluid inside the middle ear can be drained [2]. This surgery is usually done in the operating room since it is normally needed to put the patient under general anesthesia (GA). However, like most surgeries done in the operating room, the conventional surgical treatment for OME has several disadvantages [3–5]: (i) risk arising from the use of GA; (ii) highly dependent on surgeon's skills; (iii) high costs (approximately US$2,000 per surgery [6]); (iv) reduced access for patients and (v) treatment delay. To overcome these disadvantages of the conventional surgical treatment, the office-based surgical device offers a good solution.

Over the past decades, a number of office-based devices have been developed for assisting the surgeon to carry out myringotomy or/and tube insertion which can be found in [3–5] and [7–11]. However, manual operations are still needed while using these devices, i.e., they require surgeon with special skills. Moreover,

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no sensing and control systems are developed and incorporated in all these devices, leading to low precision and intelligence. To this end, a novel precision office-based surgical device involving sensing and control systems has been developed in [12]. The proposed device allows the office-based, automatic, precise and quick surgical treatment (myringotomy with tube insertion) for OME to be administered to a patient under LA.

However, due to the office-based design, the proposed device cannot subject a patient to GA once the surgery is shifted to the office. There are challenges involved while carrying out an office-based procedure on an awake patient. One key factor to a high success rate is to keep the relative motion between the device and the patient's head or TM small after the tube touches the TM. This is because that motion will affect the contact force and then affect the success rate. More specifically, the procedures may not be successful if the contact forces are out of the allowable threshold. An excessive contact force may result in over-insertion while a zero or small contact force may lead to under-insertion. Significantly, an excessive contact force may also lead to large discomfort or even injury on the TM. Thus, an effective motion/force stabilization is required. An approach for stabilization is proposed in our previous work [13], combining mechanical restraints and physiological engagement, which can be leveraged on at different times with a strategy to encourage the patient to participate in the process while using the device. This approach helps to stabilize the device directly and reduce the patient's head motion, but it is still not able to guarantee that the relative motion between the tool set (with tube) of the device and the TM is minimized and the contact force meets the requirements. Moreover, the mechanical restriction is not the best solution since the patient may feel uncomfortable or hurt. Thus, a new approach for stabilization by forcing the tool set to follow the TM to sustain a desired contact force can be considered.

To this end, a force feedback can be considered for addressing the stabilization challenge. Recently, several research works that relate to the force control system or stabilization system for surgical devices have been developed in [14–17]. In [15], a haptic feedback system in robot-assisted minimally invasive surgery was described. In [16], a hand-held surgical device with a robotic force tracking system was developed for maintaining a desired contact force in beating heart. In [17], researchers proposed a force control system for maintaining a desired contact force between the target tissue and the probe of the probe-based confocal laser endomicroscopy (pCLE). As evident, a force control system can benefit the surgery and improve the stabilization and the performance of the surgical device. However, all these systems are not designed for OME and their target is not focused on the contact force on the TM neither. Additionally, as mentioned previously, there are few studies on the stabilization of the office-based surgical devices for OME. Thus, the development of the stabilization system for such kind of devices is required and a stabilization system based on force feedback is proposed in this paper. Nevertheless, some researchers suggested that the response of the force control system may not be fast enough for robotics and surgical applications [16,18]. Moreover, it is suggested that the use of visual servoing can improve the force control system performance [19]. Thus, vision feedback is proposed and designed in this paper for speeding up the response and achieving better performance.

In this paper, a new stabilization system using force and vision feedback is developed for the proposed surgical device. The main contribution of this paper is to develop a method using the force and vision feedback to realize the new stabilization system for the novel surgical device, so that the effects of the head motion can be minimized and the performance and the safety of the surgical device can be guaranteed. The rest of this paper is organized as follows. First, the proposed surgical device and its working process are introduced in Section 2. Next, the human head motion are studied in Section 3. In Section 4, the development of the control scheme for the stabilization is presented in detail. Then, experiments and results on force tracking and stabilization are given and discussed in Section 5. Finally, conclusions are drawn in Section 6.

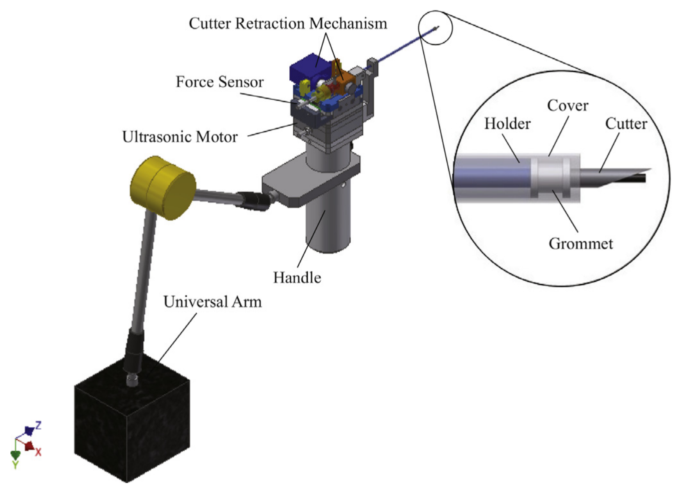

Fig. 1. Surgical device for OME.

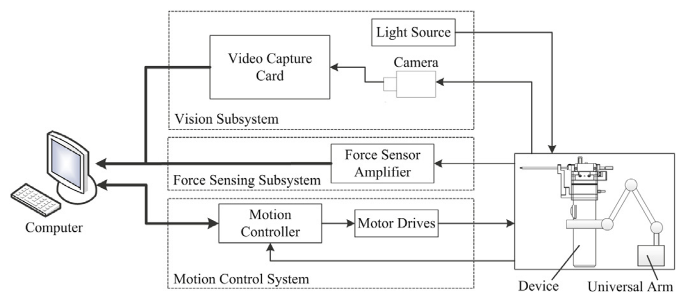

Fig. 2. System architecture.

2. System description

In this section, the proposed surgical device for OME is introduced at first and followed by the presentation of its working process.

2.1. System architecture

The surgical device for OME and the system architecture are shown in Figs. 1 and 2, respectively.

The proposed surgical device is controlled by a computer and mainly consists of three systems which will be presented in the following subsections. The working prototype of the proposed surgical device has been built. Large numbers of tests have been done on the mock-up system (ear model with mock membrane) using the prototype, which show that the success rate of up to 100% can be achieved. Currently, the regulatory testing for the device and the preparation work for the first-in-man clinical trial are ongoing.

2.1.1. Mechanical system

It is designed carefully to address the challenge of limited space inside the ear canal. Significantly, the cover, the holder and the cutter with the grommet (tube) are integrated tightly and compactly into a telescopic structure design. The cover is at the outer core followed by the tool set (the holder and the cutter) and the cutter is inside the hollow of the holder. This design minimizes the size of the required tools and allows all of them to enter the