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8 authors, including:

Kai Huang
University of Science and Technology Beijing

Mingchuan Zhou
Technische Universität München

Carolina Lajblich
Technische Universität München

Haotian Lin
Zhongshan Ophthalmic CenterSun Yat-Sen University

A Flexible Head Fixation for Ophthalmic Microsurgery

Kai Huang[1], Mingchuan Zhou[2], Carolina Lajblich[3],
Chris P. Lohmann[3], Alois Knoll[2], Yehua Ling[4], Haotian Lin[5], and M. Ali Nasseri[3]

Abstract— **Ophthalmic surgery is a typical microsurgery, where the surgical progress imposes huge challenges on delicate operations to surgeons. The fixation plays an important role in restriction the head movement and also providing a friendly interaction with both patients and surgeons. A fixation specific for ophthalmic robotic set-ups is developed in this paper for a hybrid parallel-serial robot. Evaluations for the benefits of the fixation device are performed with an optical tracking system. The experimental result shows that the designed fixation can restrict an average of absolute movements below 10 mm.**

I. Introduction

The present situation of eye pathologies, which contributes to more than 280 million visual impairments [1], raises an increasing demand for the ophthalmic surgery. Vitreoretinal surgery is a typical ophthalmic surgery consisting of complex manual tasks. The incisions, created by keratome and trocar at the sclera in a circle and 3.5 mm away from the cornea center, are made to provide the entrance for three tools: light source, surgical tool, and irrigation cannula [2]. The irrigation cannula is used for liquid injection to maintain appropriate intraocular pressure. The light source is used to illuminate the intended area on the retina, allowing the planar view of the area obtained and analyzed by surgeons through the microscope. The surgical progress imposes huge challenges on delicate operations to surgeons.

In order to work around these challenges and assist surgeons to obtain better surgical results, robotic platforms specified for ophthalmic surgery have been developing for more than 25 years [3]–[6]. Regardless of which kinds of surgery robots will be applied in the clinical application in the future, the fixation is an essential instrument that constraints the patients head during the ophthalmic surgery. In principle, the design of fixation should have following requirements: a) The fixation is supposed to secure the patient with respect to the robotic basis, fulfilling certain medical standards such as being non-traumatizing, non-invasive, safely, easy, and intuitive within the clinical environment. b) The fixation of the robot has to meet medical hygiene requirements. The exposed surfaces need to be wipe-able and offer at least a possibility for safe coverage with surgery drape and infecundity. c) The working space during the surgery [7] can not be implicated with the usage of the fixation. Therefore, the head fixation should be carefully designed.

In the literature, unwanted head motions of patients during robot-assisted eye surgery have also been discussed. Wei et al. [4] presents a concept for head positioning in relation to the robot via a bite plate. The locking bite-plate in the patient's mouth and additional coronal straps secure a frame to the patient's head rigidly. Meenink et al. [8] proposes a head immobilization concept also used in radiotherapy in combination with conventional ophthalmic head rests. Precut thermoplastic head masks are heated and shaped around the patients head by stretching. After cooling down, the mask is pulled towards the table and becomes more rigid and tight fit around the patient's head with cutouts around the treated eye. The mask is mounted on three to four fixations at the operating table during the radiotherapy. The personalized molding of the mask takes about 5 min for mounting and is non-invasive. The mask fixes the patient within a 2.0 ± 0.5 mm constraint during radiotherapy [9].

In this paper, we propose an air-cushion based fixation which is specially designed for the IRAM!S robot [5]. Our head fixation is easy for setup and fine adjustment. It demonstrates one way of realistic clinical or realistic pre-clinical testing of the IRAM!S robot. The contributions of this work are summarized as follows.

- A new concept of fixation for robot-assisted ophthalmic surgery is introduced, where a modular integration of the fixation enables security, ease of setup, and fine adjustment of the robot through the fixation device.
- We design the experiment with an optical tracking system to validate the constraint ability for patient's head safety.

The rest of this paper is organized as follows: Section II shortly describes the background of the IRAM!S robot. The proposed design is introduced in Section III. Then Section IV gives the experimental evaluations to prove the functionalities of design and Section V concludes the paper.

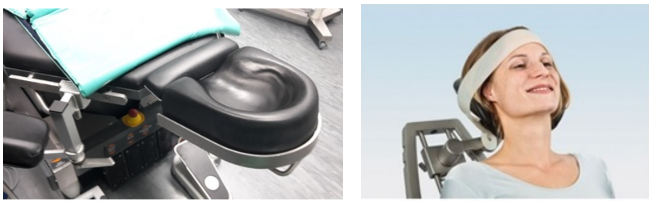
II. Background

The consideration of a new device into an existing operation room requires consideration of the current operating room layout. An overview of the typical operation room layout is described in [10] for eye surgery for the integration of master-slave robotic device. This idea of mounting the robot directly to an existing operating table is preferable.

In the IRAM!S setup at the *Klinikum rechts der Isar*, there are different models of operating tables for ophthalmology which consist of the main body couch and the head rest.

Authors Affiliation: [1] Sun Yat-Sen University, School of Data and Computer Science. [2] Technische Universität München, Fakultat für Informatik. [3] Technische Universität München, Klinikum rechts der Isar. [4] Guangxi Normal University for Nationalities, College of Physics and Electronic Information Engineering. [5] Sun Yat-Sen University, Zhongshan Ophthalmic Center, State Key Laboratory of Ophthalmology.
Email: huangk36@mail.sysu.edu.cn, mingchuan.zhou@in.tum.de, carolina.lajblich@tum.de, chris.lohmann@mri.tum.de, knoll@in.tum.de, lingyehua@163.com, haot.lin@mail.sysu.edu.cn, nasseri@mri.tum.de,

Especially the design of the latter provides access to the patient's eyes for the surgeon and medical personnel while safely supporting the patient's head. It limits the motion of the head to a small rotation and consists of a cup or half round "horseshoe" shape, see Fig. 1(a). During ophthalmic surgery the patient's positioning is generally supine under general or local anesthesia eventually with the head about 5-10° downwards and the arms positioned. In clinical routine, possible movements are reduced by an additional fixation of the patient with a fixation strap from plastic or silicone, see Fig. 1(b). This setup serves as a base for our head fixation device.



(a) (b)

Fig. 1. (a) Currently used operating table (UFSK-International OSYS GmbH, Regensburg, Gemany) in the OR at the Klinikum rechts der Isar and (b) the principle of head fixation tape (BRUMABA, Wolfratshausen, Germany)

III. Fixation Device Design

The main idea of our design is to integrate the fixation of the head into the holder device for the ophthalmic robot. Therefore our work consists of two parts, the fixation of the robot and the fixation of the head of the patient in relation to the robot. Fig. 2 depicts the overview of the fixation and we will explain piece by piece in details in this section.

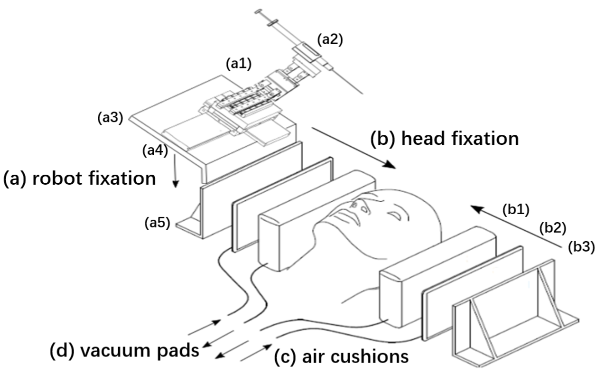


Fig. 2. Overview of the fixation device.

A. Robot fixation

The Robot fixation is depicted in part (a) of Fig. 2. The iRAM!S robot consist of a linear slide that holds and guides the robot holder on its main movements along the patient's head. The slide is fixed on a plate with eight screws. The plate is positioned angular to the patient's vertical head axis to guarantee that the robot's working volume of 50×50×50 mm will cover the operated eye during procedure.

The robot is partly above the patient's eye and forehead placed on the head rest. It means that the robot ((a1) in the figure) itself cannot be mounted pre-surgically onto the operating table before the patient is in supine position. As the tool holder and the manipulating surgical instruments (a2) themselves have a certain length depending on the surgical tool used, the robot fixator is designed adjustable in the horizontal direction. A fixed vertical plate (a3) supports the robot fixator vertically. Its horizontal position is moved towards the patient to position the robot (a1) next to the head. It defines its general position.

The robot fixator concept considers a removable angular plate (a4) where the robot is screwed to. Screwing the robot to the angular plate (a4) of the robot fixator directly firstly during surgery is impossible due to various risks, e.g., injuries, quickness, safety. Hence, the plate (a4) is easily removed directly after surgery by the surgeons with an ergonomic and easy handling. The concept foresees a fixed mounting (a5) to an existing operating table as well as a mounting to a single head rest for training purposes. Current head rests can vary in shape and need individual adaption of the fixation.

B. Head fixation

Our head fixation, as shown in part (b) of Fig. 2, is a rapid, non-traumatic fixation of the head during surgery, suitable for all head shapes. As the patient is in a supine position, a direct non-invasive fixation of the head is realized against the upper jaw of the patient's skull. Lower parts of the skull such as the lower jaw are moveable and therefore unfavorable for an easy external fixing.

Because the upper jaw of different patients is different in size and shape, requiring an individual adaptation of the fixing unit for fixing, a personalized adaptation is performed prior to operation similar to dental molds or a dental jaw impression. The skull is fixed indirectly via the upper jaws and the scalp by adaptable cushions (b1 in Fig. 2). Due to their granulate-filling, their shape is easily adaptable. To enable a horizontal fixing movement of the cushions (b1), two vertical plates (b3) are fixed laterally to the head and press the molded cushion towards the patient's head. As the cushion expends towards the upper jaw of the patient, pressure will be applied accurately to the patient‘s head. Fitted air cushions (b2) are fixed between the moldable pads (b1) and the vertical plate (b3). When inflated or deflated, they adjust and stabilize gently the pressure towards the patient's head in case of horizontal backlash. Notes that the friction between the scalp and the fixator has to be avoided.

C. Operation of fixation device

At the beginning of an eye-surgery, medical staff and anesthetist prepare the patient for surgery. The patient lies down onto the operation table in supine position and his occiput rests at the head rest. Two vertical plates stand laterally to the head at the open position. One covered vacuum-pad is fixed between the plates and the head on either side. The vertical plates are moved towards the patient until the soft vacuum-cushions touch the patient's head. The vacuum-pads contain fine-granulated particles and air at the beginning as their valves are open. The vacuum-pads are evacuated (part (b) in Fig. 2) manually by the nurse or the assistant using a pump. The granulate forms an individual impression of the patient's side jaw and skull and the surface of the cushion hardens. The position can be re-arranged and the impression can be adjusted by more or less air left in the pads. Afterwards, the valve is closed. The medical assistant inflates the two unfilled air-cushions (part (c) in Fig. 2) between the vacuum-pads and the vertical plates manually and closes their air valves. The resulting backlash between the now rigid vacuum-pads and the stabilizing vertical plate is eliminated. This light pressure of the shaped vacuum-pads locks the patient's head into its position.

The fixation of the patient's head can also be realized when the patient is fully conscious. A fine adjustment and the manual inflation of the air cushion can be performed by the patient directly with the help of the medical staff to close the valve. After the fixation of the head is realized, surgery preparation is continued such as anesthesia, control units and the microscope are positioned. The patient's eye is exposed for surgery. Just before the start of the operation, the surgeon places the robot fixator on the designated place on top of the vertical support (part (a) in Fig. 2). The position of the robot is the fixed and the robot can be controlled to perform the surgery.

After the surgery is finished, the surgeon removes the robot with the robot fixator from the device and placed on the instrument table. In order to release the head, the fixation can be opened by the air-valves of both air-cushions and vacuum-pads, parts (c) and (d) in Fig. 2, respectively. The valves of the cushions are opened in reverse order and the plates are moved to their outer position. The patient can rise his head without seeing robot manipulators above his head and eye or other risks for injuries.

D. Realization and design of fixation device

In order to test applicability, a prototype is designed based on the same functional concept but offering a more realistic clinical set-up. For the new prototype fixation device, aluminum has been chosen over plastic or synthetic materials due to availability ease of manufacturing and standardization for test set-ups. A further anodizing of the aluminum components enables surface finishing suitable for medical environments. Anodizing applies a protective coating for regular use of aggressive hygienic cleaning, color and sterilization of the aluminum parts by forming an oxide film on the surface through electrolytic passivization. The setup of the prototype is shown in Fig. 3.

IV. EXPERIMENTS

To evaluate the immobilization, the Passive Polaris System with Model P4 Position Sensor from NDI, Ontario Canada, is used, which is a real-time tracking system for passive markers. The system includes a position sensor, a power supply unit and different passive markers. Retroreflective

Fig. 3. The prototype in the operation theatre.

targets are mounted to wireless tools. The position sensor provides infrared light through illuminator rings' surrounding each lens cell of the position sensor by infrared, light emitting diodes. Passive markers are tracked by the system through reflection of the light that is returned directly to the position sensor. The position sensor controls the infrared field and derives the position and orientation of each tool by comparison of its reflection and the previously loaded tool-calibration data. The system offers a volumetric accuracy up to 0.25 mm [11] at and operates at frequency 20 Hz. The experimental setup is shown in Fig. 4.

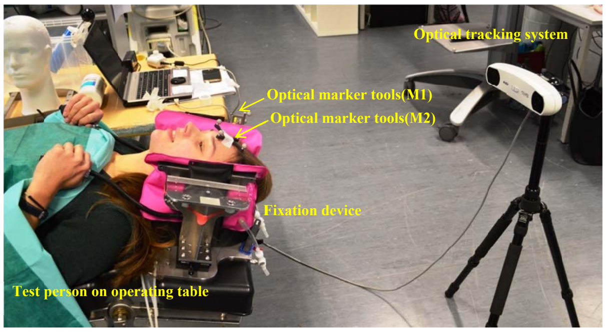
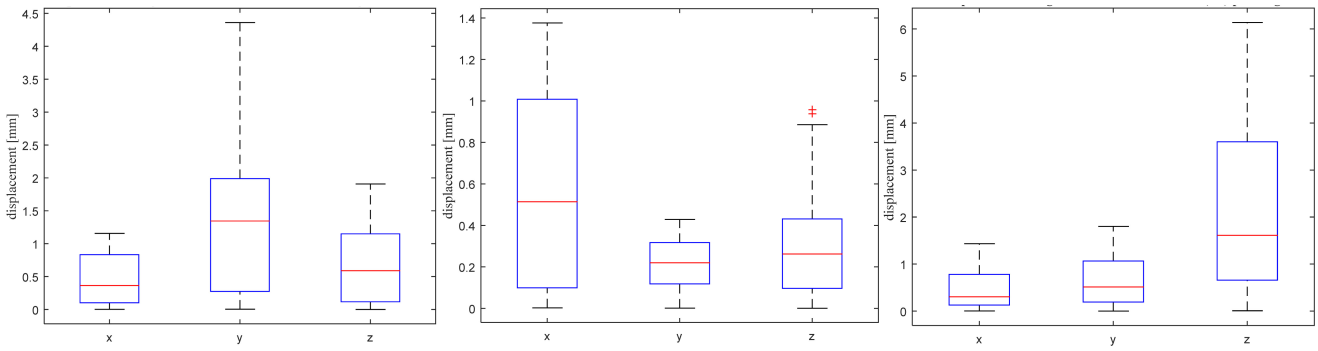


Fig. 4. The experimental setup for movement evaluation. Optical marker tools M1 is fixed on the head fixation, and M2 is mounted on the experimenter.

Movements that cannot be restricted by the fixation device will be seen by the change of distance between the fixation device and the fixated head. Three kind of movements (a) left/ right movement, (b) lifting movement and (c) pitching movement are tested and the movement from the head relative to the reference of fixation are presented in Fig. 5. The head turn to the left and right is dominated by translation in positive and negative y- direction indicating whether the head turns left or right. The lift of the head creates a negative x- translation. The pitch shows deflection in positive and negative z- and y- direction.

Fig. 6 presents the the value ranges for each of the movement types are displayed in x-, y- and z- direction exemplarily for the measurement in Fig. 5. The specification of the different components of the movements is used to understand the single translation better and how they are restricted or enable movement. The turning movement shows



(a) (b) (c)

Fig. 6. Box and whisker plots for displacement range of one measurement for (a) turning, (b) lifting and (c) pitching.

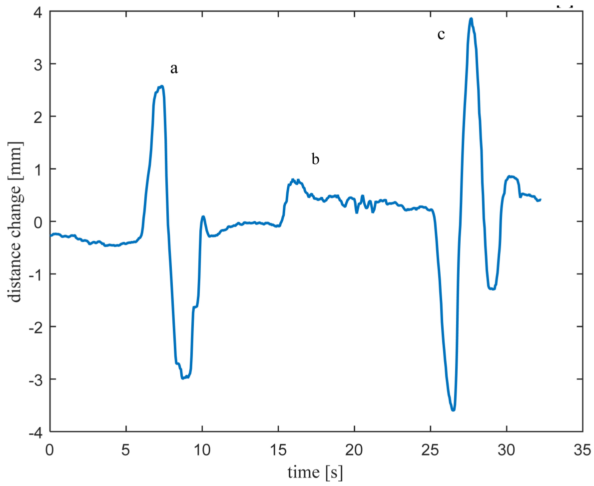


Fig. 5. Exemplary displacement of immobilized head over time in different coordinate directions for the assessed movements: (a) turning left/right, (b) lifting and (c) pitching.

the highest range of motion of 4.39 mm in y- direction while the percentile of 75% of the values stays within 1.95 mm. The x- and z- direction are relatively small, which is also seen by the movement curves. For the lifting movement the range is similar to the length distribution: maximal movements do not exceed 1.39 mm for x- direction. The boxplot of the z-axis shows outliers whose data is not within the minimum and maximum whisker. Quartiles display that displacement in these directions are very and close to camera accuracy of 0.51 mm. For the pitching movement the maximal range of head movement in z- direction is 6.14 mm, whereas 75% of the values of head displacement are within 3.65 mm.

V. Conclusion and Future Work

We design a head fixation for the iRM!S surgical robot and perform the primarily evaluation for the device. Among all the metrics for a design of fixation, the maximal restricted ranges of motion of all movements is the most important criterion. Therefore six measurements for one test person following the same testing protocol are taken into considerations. For x- and y- direction maximal translation are below 2.6 and 4.5 mm. The measurements' median is near to zero, indicating that to 75% of the time movement has been restricted to below 1 mm. It is shown that no translation is over 10 mm. On average, absolute movements have been restricted to below 2 mm. In the z- direction, the movement is mainly restricted by the friction of two soft vacuum-cushions, thus the movement of pitching will cause relative large displacement with 6.14 mm.

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