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A new evaluation and training system for micro-telemanipulation at the middle ear

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Abstract— **In this article, a new surgical model for evaluating telemanipulators used in middle ear surgery is presented. The purpose of this work was to develop an evaluation and training system which imitates a typical surgical task of middle ear surgery and which can easily be repeated in order to get significant result. The abstract task can be performed manually or by means of a microsurgical telemanipulator and guaranties stable experimental conditions between different subjects at any time. As a task the stapedotomy was chosen, due to the high demands in positioning and in applying forces to the delicate structures in the middle ear. The manual and telemanipulated performance of 15 ENT surgeons and 17 medical students was compared using this evaluation and training system.**

I. Introduction

Microsurgical interventions at the middle ear are very challenging for the surgeon due to the small size of the structures that are operated on, such as the malleus, the incus, and the stapes. Operating microscopes and special micro instruments are used for these delicate tasks [1]. The stapedotomy, for example, is a microsurgical technique for treating conductive hearing loss owing because of ossification of the oval window. Through stapedotomy, the stapes is replaced by a small titanium prosthesis. Therefore a small hole (Ø 0.5mm) must be pierced into the stapes footplate using a micro pick (also drilled or lasered) and the prosthesis (Ø 0.4mm) has to be inserted. In [2], [3] the authors presented a micro-telemanipulator (MMS-II) for middle ear surgery. It is small-sized, lightweight, and capable of moving standard instruments of ENT surgery with very high precision in three degrees of freedom. The system can also be used as a measuring device [4]. It is supposed, that surgeons can improve their skills using this manipulator in certain highly challenging tasks, such as the stapedotomy. A surgical model is needed for proofing this assumption. Several surgical models have been developed or used for evaluating microsurgical telemanipulators. Human temporal bones have been used in [5] for simulating a stapedotomy. The RAMS-System was evaluated using an abstract task where plates with 0.076 mm had to be touched with an instrument [6]. An FEM-based computer model and a motorized model of an eye was used for evaluating the *Micro Surgical Robot* [7]. An evaluation system for the MMS-II should consist of a simple task that can easily be repeated under constant conditions. Nevertheless it should be realistic enough to simulate typical constraints (limited access to the operational field, adverse hand posture, limited view of the region of interest). The precision of instrument guidance should be analyzed as well as the force applied during the task for analyzing force tremor. Data acquisition and analysis should be automated.

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II. Description of the Evaluation and Training System

A. Preparation Task

Perforating the stapes footplate was used as a basis for designing the preparation task. The diameter of the hole which has to be pierced is about 0.5 mm. The instrument force is about 2 N. The tremor of the hand results in a displacement of about 0.1 mm under optimal condition. Force tremor stresses the inner ear during preparation and was found to be about 0.05 N. The task was therefore defined as follows: 1) Small holes (Ø 0.5 mm) have to be hit with a standard surgical pick (Ø 0.4 mm). 2) A force in the range of 1.47 N to 1.96 N has to be applied. Optical signal appears if the hole is hit successfully (yellow) and at the same time the force is in the valid range (green). Optical signal (red) appears if the surrounding area of a hole is hit instead of the hole itself. Optical signal appears (red) if the force exceeds 1.96 N.

B. Implementation

The evaluation and trainings system (ETS) consists of artificial temporal bone, a sensor electronics and an evaluation electronics (Fig. 1). The artificial temporal bone is 3D-printed from a CT-dataset. At the end of the ear canal the sensor electronics is situated. It consists of an electrical conductive error plate with seven small holes (Ø 0.5 mm), an electrical conductive success plate and three force sensors (Fig. 2). The subject has to touch the success plate without touching the error plate with a micro-pick instrument. The success plate is mounted onto three force sensors (FSS1500NSB, Honeywell) which detect the applied force. The sensor electronics contains a microcontroller, which detects if the error plate or the success plate has been hit and receives the force values of the force sensors. The sensor data is used to control the signal lights for the subject. The sensor electronics also sends the applied force F, the status of the success plate (I_T) and error plate (I_F) to an external computer for data analysis.

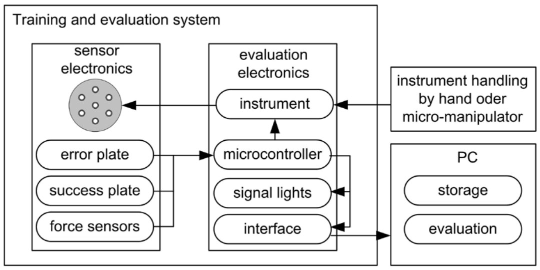

Figure 1: Block diagram of the components of the ETS.

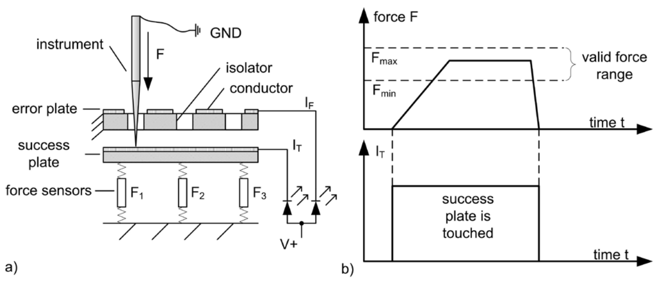

Figure 2: Sensor electronics: a) general setup and b) signal output.

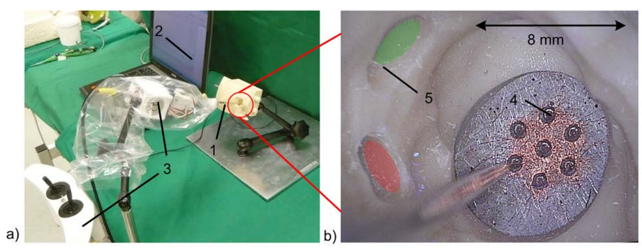

Figure 3: Evaluation and training system: a) overview b) detailed view.

Data analysis

The incoming data from the sensor electronics is stored with a time stamp by an external computer. After each trial of a subject five characteristic values are calculated automatically using Matlab (Mathworks, Matlab 2007a) scripts: 1) number of errors 2) duration for task completion 3) maximum force 4) number of force oversteps 5) force tremor.

Number of errors: An error is counted if the micro-pick touches the error plate, no matter how long this takes. Between two errors there must be a minimum of 100 ms without error; otherwise both errors are counted as one.

Duration for task completion: This is equivalent to the length of the dataset of one trial.

Maximum force: The maximum force during one trial of one subject.

Numbers of force oversteps: A force overstep is counted if the applied force F is larger than 1.96 N and afterwards within any time gets smaller than 1.76 N. The hysteresis of 0.2 N works as a debouncer.

Force tremor: To determine the force tremor, the root mean square (RMS) value of the force *F(t)* is analyzed. Arbitrary changes in the force (< 5 Hz) should not be taken into account. Because the amplitude of the arbitrary force has large amplitudes (2 N) compared to the tremor oscillation (0.05 N) the force signal has to be high-pass filtered. A low pass filter (Chebyshev Type II, 1. order, cutoff-frequency 5Hz) was used therefore. The force F was filtered forwards and backwards for compensating the typical frequency-dependent phase shifting of that type of filter. This results in a squared transfer function and a doubled filter order. The filtered signal is subtracted from the original signal afterwards (Fig. 4).

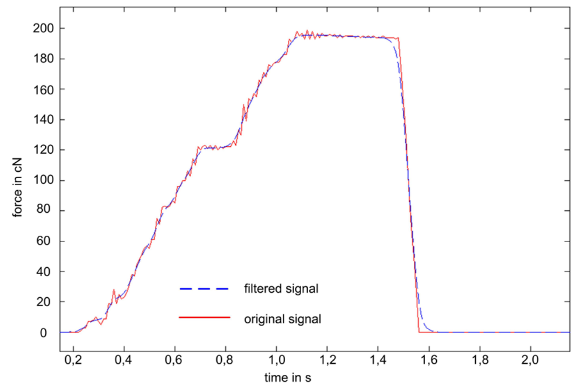

Figure 4: The force signal F from a manipulator trial filtered with a low-pass filter is superposed with the unfiltered signal. Both signals are subtracted from each other for further processing.

Force values that are zero and force areas with a large slope angle are removed in order to achieve a valid raw signal for calculating the RMS-value with equation (1).

$$RMS_{tremor} = \sqrt{\frac{1}{N}\sum_{i=0}^{N-1}(F_{tremor}[i])^2} \qquad (1)$$

III. EXPERIMENT DESIGN

A. Experimental setup

The following equipment has been used (Fig. 5): Micro-manipulator with perforator instrument (0.4 mm), training system, human torso model, exoscope (Vitom, Karl Storz, Germany) with HD-camera and HD-monitor, surgical microscope (Carl Zeiss, Germany). We chose two different imaging technologies (exoscope and microscope) because they differ in 2D/3D visualization, monitor/ocular display and the general surgical setup.

Figure 5: Experimental setup for telemanipulated instrument guidance using a microscope as imaging device.

Thus every subject had to perform four different trials:

1) Telemanipulated instrument guidance using a microscope.
2) Telemanipulated instrument guidance using an exoscope.
3) Manual instrument guidance using a microscope.
4) Manual instrument guidance using an exoscope.

As subjects 17 medical students and 15 micro-surgeons specialized in the field of ENT took part in the experiment. For every trial they had to pierce 120 times into the holes of the training system as described in the preparation task before. The completion of one task took about 6 to 15 minutes. Between the tasks the subjects had enough time for regeneration.

B. Statistics

Outcome variables were arsinh-transformed prior to analysis in order to approximate normally distributed variables. A mixed model analysis of the outcome variables using experience status (surgeon (1) vs. student (0)), endoscope (1) vs. microscope (0), and manual (1) vs. manipulated (0) as fixed effects and subject as random effect was performed. Also a subgroup analysis of the "manual" and "manipulated" subgroups was performed to analyze the influence of the experience status on the performance separately for these two devices. This difference was analyzed analogously to the outcome variables. The level of significance was set to 5%.

IV. Results

The results are graphically shown with boxplots using the median, 5^{th} percentile, 95^{th} percentile, maximum and minimum values.

A. Positioning accuracy: manual vs. telemanipulator

The number of errors has been reduced by 76% in median using the manipulator compared to manual instrument guidance ($P < 0.001$). At the same time the duration of task completion was increased by 250% ($P < 0.001$).

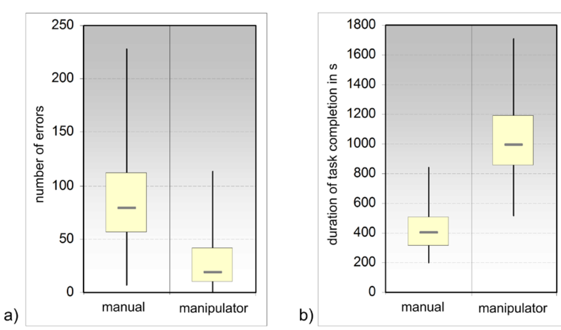

Figure 6: A better positioning accuracy with the manipulator results in an increased preparation time of the tasks.

B. Quality of force application: manual vs. telemanipulator

The maximum force can significantly be reduced using the manipulator ($P = 0.0213$). However the overall number of force oversteps was increased slightly ($P = 0.0004$). More dominant was the reduction of the force tremor (RMS) by 59% in median using the manipulator ($P < 0.0001$).

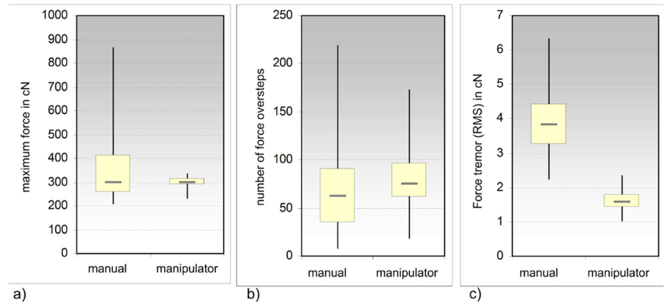

Figure 7: The force tremor (RMS) was reduced by 59% when using the manipulator. Maximum force and number of force oversteps differ significantly but only slightly.

C. Influence of the experience: students vs. surgeons

Manual instrument guidance: The experienced surgeons did 62% less errors in median than the students ($P = 0.0230$) when using the telemanipulator. All the other parameters (RMS, maximum force, number of force oversteps, task time) did not differ significantly.

Telemanipulated instrument guidance: When using the manipulator there was no significant difference between students and surgeons. Looking only on the manipulator's performance, the students were able to reduce the number of errors with the manipulator more than the surgeons. The students improved by 84% in median ($P < 0.0001$), the surgeons improved by 50% ($P = 0.0009$).

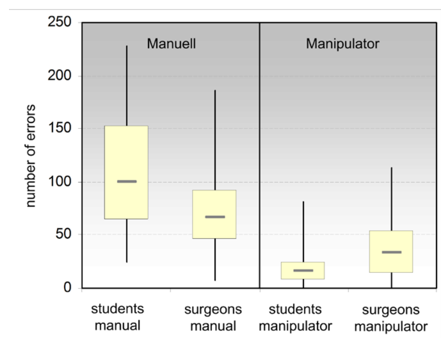

Figure 8: Both, students and surgeons did improve their performance using the manipulator. There was no significant verifiable difference between both groups anymore in any parameter when both groups used the manipulator.

D. Influence of the imaging system: exoscope vs. microscope

Manual instrument guidance: The subjects did 30% less errors in median if a microscope was used instead of an exoscope ($P < 0.0145$). The duration of task completion was 20% higher in median when using the exoscope ($P < 0.0001$). The maximum force was 20% higher in median when using the exoscope however the force tremor (RMS) was 14% smaller ($P < 0.0001$).

Telemanipulated instrument guidance: The subjects did 40% less errors in median when using the exoscope instead of the microscope ($P=0.0265$). All the other parameters did not show any significant difference comparing preparation performance with microscope and exoscope.

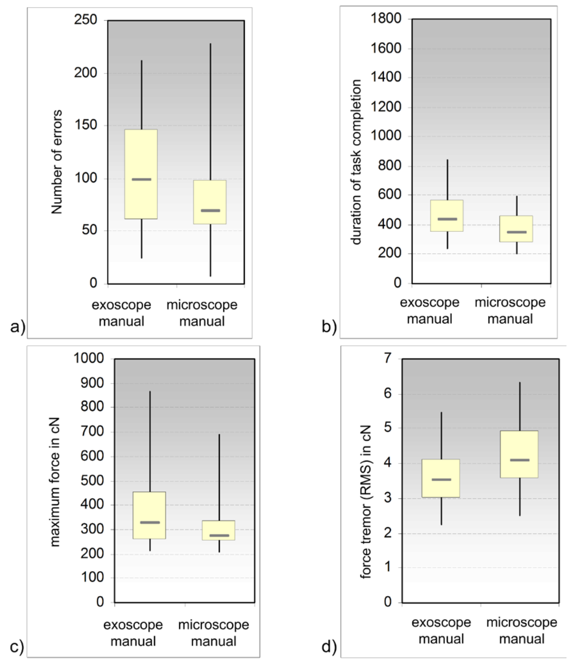

Figure 9: During manual instrument guidance the use of a microscope showed significant better results in (a) the number of errors, (b) the duration of task completion and in (c) the maximum force. Only the force tremor (c) was smaller when using the exoscope.

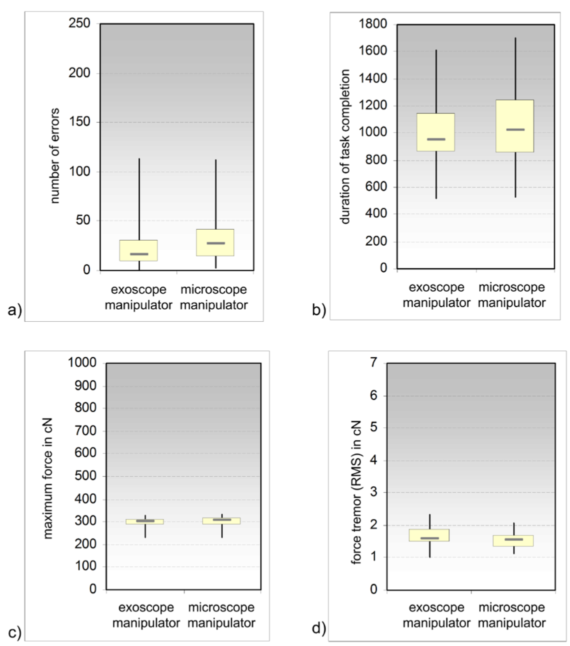

Figure 10: a) Using the telemanipulator the subjects achieved a smaller error rate when using the exoscope. All the other parameters showed no significant difference.

V. Discussion

The experiment showed that structures in middle ear surgery can be touched more precisely when using the micro-manipulator. Students as well as experienced surgeons improved their skills. The surgeons showed better performance compared to the students when the instrument was guided by hand. But when using the micro-manipulator there was no significant difference anymore. Forces could be charged in about similar quality comparing manipulator and manual instrument guidance when looking at the maximum force and number of force oversteps. However the reduction of the force tremor when using the manipulator was very clear. The micro-manipulator and the exoscope seemed to be a good combination. For manual instrument guidance the microscope was superior in most parameters. The improvements with the manipulator have to be paid with a longer duration of task completion.

VI. Conclusions

In this article, a new evaluation and training system for microsurgical interventions at the middle ear was presented. The system is intended to compare the performance of manual and teleoperated instrument guidance. 15 surgeons and 17 students evaluated the micro-manipulation system MMS-II by means of the new evaluation and training model. It was found that the MMS-II system significantly improves the quality of instrument guidance in respect of positioning and force application. This result did not depend on the experience of the subjects or the technology of imaging.

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