Development of a usability test for testing handles of microsurgical instruments used in ILM peeling

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Abstract: The aim of our work was to develop a procedure for testing the usability of various designs of microsurgical instruments used in the peeling of the internal limiting membrane (ILM) of the eye. In a first step, a hierarchical task analysis (HTA) was used to identify critical factors in ILM surgery. Findings of the HTA were used to specify a test equipment enabling to assess experimentally the usability of the instrumentation used in ILM peeling. In a second step, a test equipment was build according to the specifications defined in the first step. Finally, the test equipment was validated experimentally using 11 participants by comparing accuracy in a manual task, while using either the dominant or the non-dominant hand. Results on manipulation errors and speed support validity of the setup for testing the usability of microsurgical instrumentation.

Keywords: usability, hand-held tool, manual task, microsurgery, surgical instrumentation

1. Introduction

The deterioration of visual performance in the elderly eye, may be caused by various factors. Presbyopia, cataract, senile macula degeneration, or degeneration of retinal receptors due to diabetes are prevalent causes for a reduced visual performance with age. For some age related vitroretinal diseases, like for the so called macular hole, the surgical therapy includes a removal of the inner limiting membrane (ILM) covering the retina. The ILM removal, termed ILM peeling, is a highly challenging intervention, even for experienced retina surgeons. It consists in grasping the ILM by means of a microsurgical forceps which is mounted on the tip of a handle. Once the ILM is grasped, it is removed by a visually controlled, swinging movement of the forceps grasping the ILM. The movement should be such as not to tear off the membrane. In order to avoid a trauma of the retina, the procedure requires a precise motor-control of both hands of the surgeon. One hand manipulates the handle with the forceps and the other hand is used to hold a light source in place, which is introduced into the patient's eye for lighting up the location of the microsurgical intervention. As the light source emits directional light, the forceps cast a shadow on to the retina. The shadow is used to estimate the distance of the forceps from the surface of the retina. Since the casted shadow depends on the position and orientation of the light source, the position of the forceps and the structure of the part of the retina receiving the shadow, a proper estimation of the distance of the forceps from the surface of the retina is only possible after intense training. According to statements of experienced surgeons, quality of the surgery solely depends on precision in motor-control, and there is no speed-accuracy tradeoff affecting task performance. For this reason, popular speed-accuracy tradeoff measurements, such as Fitts' task (Fitts PM, 1954, EN ISO 9241-9), are not applicable in testing microsurgical instrumentation.

Ergonomics of hand-held tools has been discussed in various literature (e.g. Strasser H (editor), 2007). However, only few papers in the literature report about factors affecting ergonomics of hand-held microsurgical instrumentation, in which forces in haptic feedback vary by magnitudes from feedback forces when using hand-held tools in everyday tasks. As for instance in retinal surgery, 75% of forces are less than 7.5 mN in magnitude, of which only 19.3% are perceived by the surgeon (Gupta PK, 1999). Such weak forces as in microsurgery are about 100 times less than forces (0.5N – 0.8N) appearing when pressing a key of a PC keyboard (EN ISO 9241-4).

Methods to assess performance in microsurgical tasks focus on the effect of visual feedback and the role of tremor and investigate microsurgical tasks not comparable to the ILM peeling, as is for instance the case in a study by Rooks MD et al (1993), in which the effect of magnification of a microscope on accuracy of suture puncture was investigated. It was therefore decided to develop a new method from the scratch, which may be used to test the usability of microsurgical instrumentation as used in ILM peeling. As a first step in our development, a hierarchical task analysis (Hollnagel E, 2012) was performed to identify the subtasks of ILM peeling, possibly depending from the ergonomics of the microsurgical instrumentation. Findings of the hierarchical task analysis (HTA) were used to specify the setup for testing the microsurgical instrumentation in the laboratory. After realization, a first validation of the setup was undertaken using 11 non-surgeon participants. For this first step in validation, the hypothesis was tested, that accuracy in tasks carried out with the participant's dominant hand was better than accuracy of the same task but carried out with the participant's non-dominant hand. Furthermore, accuracy should not depend on the time for completing the task, similarly as is the case in microsurgery.

2. Method

2.1 Task Analysis

A hierarchical task analysis (HTA) was used to analyze a set of videos on ILM peeling. In addition, the HTA was supplemented with information retrieved from own interviews, which were held with vitroretinal surgeons and with information published in the relevant literature (e.g. Charles S et al, 2002). Further details on the method of HTA and results will be reported in a forthcoming publication.

2.2 Participants

In terms of a first approach in evaluating developed method for testing usability of microsurgical instrumentation, we recruited a total of 11 participants, four woman and seven men, among the acquaintances of the authors as well as among students of our university. With exception of two participants (59 y & 43 y), the participants' age ranged between 20 y and 40 y. None of the participants had experience with practice of ILM surgery. After explaining the purpose and the method of the experiment, participants gave their consent for participating at the experiment. The experiment was carried out according to the code of ethics as stated by the world medical association declaration of Helsinki.

2.3 Instrumentation

An instrument was built, by means of which movements of the tip of a microsurgical forceps could be recorded during a task, requiring the participant to carry out micro-movements similar as in ILM peeling. The instrument consisted out of two webcams (Microsoft LifeCam Cinema HD), which were fixed on translational stages (fig. 1). One camera (No 1 in fig. 1) pointed perpendicular and the other tangential (No 2 in fig. 1) to the manipulation area. Therefore, the two cameras recorded a top view and a side view of the manipulation area. A paper was placed on the manipulation area, on which a winded line was printed, indicating the path to be tracked by the participants. Four discs were printed at different locations of the winded line. The discs indicated locations along the path, at which participants were required to either close or open the forceps. The images of the two cameras were displayed on the monitor of a notebook. The top view was presented on the eft half of the monitor and was visible to the participants. The side view was presented on the right half of the monitor. Visibility of the side view was blocked, since in ILM peeling only the top view is visible to the surgeon. The videos of both cameras were stored on the notebook for later analysis. A transparent conductive film covered the paper on the manipulation area. The conductive film and the metallic tip of the microsurgical instrument were connected to an electric circuit, enabling to signalize when the tip touched the file. When the tip touched the film, a red LED (No 5 in fig. 1) lit up and a beep sound was emitted indicating a collision of the microsurgical instrument with the retina.

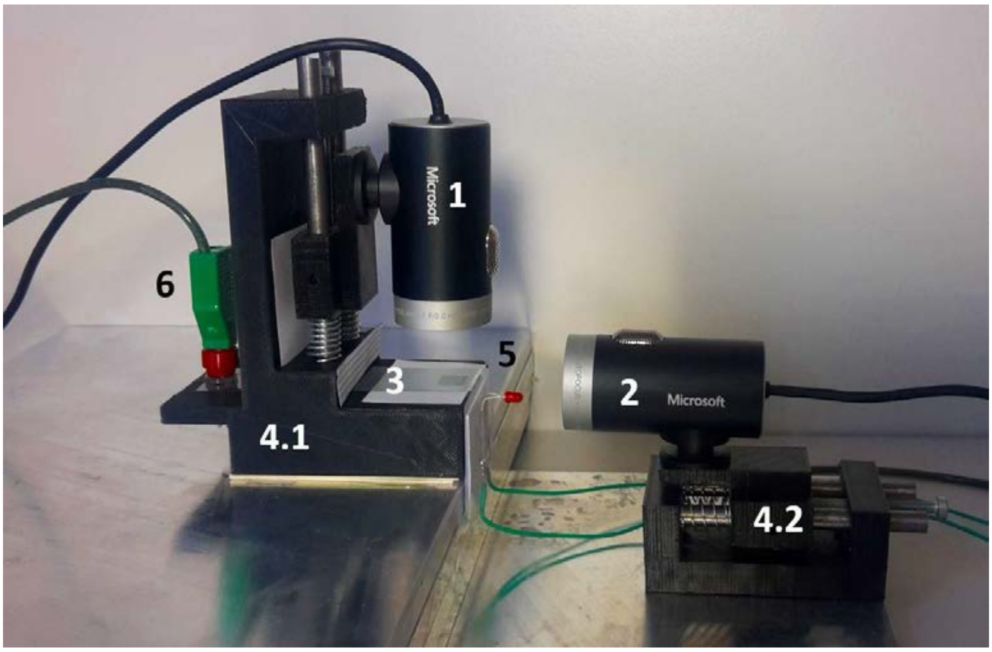

Figure 1: *Instrumentation for recording manipulations in a simulated microsurgical intervention (Neumayer NM, 2017). 1: top view cam, 2: side view cam, 3: manipulation area, 4.1 & 4.2 translational stages, 5: LED indicator for collisions, 6: connector for the conductive, transparent film covering the manipulation area.*

A printout of a horizontal grid was placed in the background and perpendicular to the manipulation area (left hand side of the number 3 in fig. 1). The grid was visible to the side view camera (no 2 in fig. 1) and was used to estimate the vertical deviation of the tip from the manipulation area.

2.4 Procedure

Participants were equipped with surgical gloves on both hands. They were asked to hold the microsurgical instrument (a Grieshaber revolution DSP ® handle equipped with a micro forceps tip) in their dominant hand and to track the path printed on the manipulation area with the tip of the instrument starting from the top end of the path and with the forceps closed. When the tip reached the first disks printed along the path, participants were required to open the forceps by pressing the spring of the handle and to continue tracking the path with the forceps open. When they reached the next disk, the spring was released and tracking continued with a closed forceps. When they reached the end of the path, participants were asked to track the path back till the start and to alternately open and close the forceps when they reached a disk along the path. As the side view was blocked, only lateral deviations of the tip from the path were visible to the participants. As is the case in ILM peeling, participants hold a pencil light source (Intralux 4000) in their non-dominant hand, which was used to lit up the manipulation area. Depending on the location of the light source and the tip, the tip casted a shadow on the manipulation area which could be used as an indicator for the distance between the tip and the manipulation area.

Participants were instructed to follow the path as accurate as possible and not to consider time to complete the task. They were told that the lateral as well as the vertical deviation of the tip from the printed path was used as accuracy measure. Also they were informed that the lighting up of the LED and the beep signaled a collision of the tip with the manipulation area and that this should be avoided with highest priority.

Before starting the measurements, participants were given enough time to familiarize with the procedure.

After completing the experiment using their dominant hand, participants were asked to redo the task holding the microsurgical instrument in their non-dominant hand and the light source in their dominant hand.

2.5 Data Analysis

Videos stored during the micromanipulation were analyzed manually. In order to measure the severity of lateral deviations of the tip from the manipulation path, a vertical and horizontal grid was superimposed to the top view video. The vertical grid separated the manipulation path in sections. For each section, the number and the amount of vertical deviations of the tip from the path were recorded, by considering the horizontal grid as reference. The time to complete the task was computed considering the video timer. Similarly, the vertical deviations of the tip from the manipulation area were measured by analyzing the video of the side view camera. In addition to the horizontal grid, which was visible in the background of the video, a vertical grid was superimposed to the video. The vertical grid served to separate the scanned path in sections, enabling to measure the vertical deviation for each section separately.

In addition to the lateral and vertical deviations, the number of times was recorded, for which the LED, which was visible in the side view camera, lit up and indicated a collision of the tip with the manipulation area.

3. Results

The counts in fig. 2 show the number of lateral deviations when using the dominant hand (blue box on the eft hand side) and when using their non-dominant hand (orange box on the right hand side). As shown in fig. 2, participants performed better with their dominant hand. A Wilcoxon test indicated a significant difference of counts of the dominant and non-dominant hand ($p<0.05$, Wilcoxon, two-tailed). Further statistical analysis showed that the number of counts is not correlated with task completion time, indicating that measured effects were not affected by a time-accuracy tradeoff.

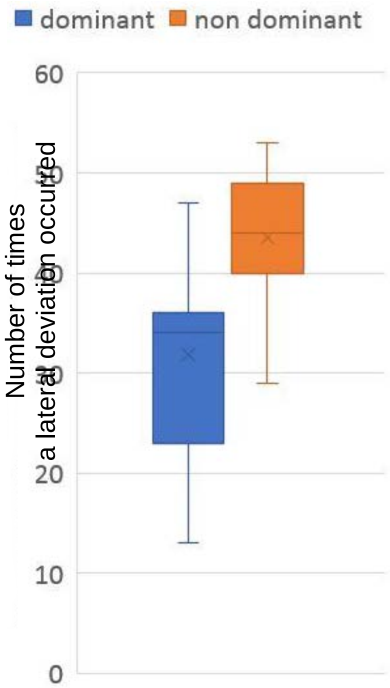

Figure 2: *Box plot representation of number of times, for which participants (N=11) deviated laterally from the predetermined path when completing the microsurgical simulation task with their dominant (left box) and with their non-dominant (right box) hand. Performance varies significantly with used hand (Wilcoxon, 2-sided, p<0.05).*

4. Discussion

Based on a hierarchical task analysis, we developed a method for usability testing of microsurgical instruments (handle and surgical tip). Testing occurs in a simulated, realistic environment and enables to quantify accuracy in a microsurgical task. As expected, performance when using the dominant hand is significantly better than performance when using the non-dominant hand. Results of other statistical analysis speaks in favor for validity of our procedure as being an ecologic and reliable procedure for testing microsurgical instrumentation. A detailed description of our method, the hierarchical task analysis of ILM peeling, and the statistical analysis of collected data on the usability test method as mentioned above will be made available in a forthcoming publication to appear in the journal Zeitschrift für Arbeitswissenschaft. Future experiments will investigate the validity of the setup using surgeons trained in the ILM peeling technique as well as surgeons trained in other microsurgical surgery (e.g. visceral surgery). Furthermore manually analysis of micromanipulation accuracy will be automatized, therefore rendering the usability testing method efficient and easy to use in the development of microsurgical instrumentation.

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