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Research Article

Effort to engage Magnification Devices in Educational Tonsillectomy - A prospective clinical trial

Abstract

Introduction: Most educational hospitals teach the tonsil surgery just with head lights and without any magnification device. This prospective clinical trial focuses on the additional workload when using a microscope or magnifying glasses for tonsillectomy.

Material and methods: four surgeons in training with no experience in tonsil surgery operated on 48 patients who underwent elective extracapsular tonsillectomy. Surgery was either performed on one patient´s side with the naked eyes plus headlamp and on the other side with magnifying glasses or a microscope. The surgeons were connected to a biofeedback device in order to monitor the breathing frequency, the heart rate variability and the masseter tone. After every operation surgeons filled out the NasaTLX questionnaire for evaluating the cognitive workload during surgery.

Results: There was a significant difference in the questioning and the heartrate variability when using the microscope compared to the naked eyes and the magnifying glasses. However, there was no statistical difference in mean operation time for all study arms.

Conclusion: Compared to loupes the mental distress is higher when operating a microscope in the first eight times. Despite the many advantages of an OR-microscope, this fact may hinder the usability of such a device in tonsillectomy.

Introduction

Tonsillectomy is still one of the most common surgical procedures in otorhinolaryngology [1]. However, over the last decades, its incidence has constantly been decreasing due to tighter indication as well as the development of alternative surgical procedures like tonsillotomy [2]. This trend mainly relies on the risks and complications which are associated with tonsillectomy: namely post-operative bleeding and pain. Primarily, non-steroidal anti-inflammatory drugs (NSAID) like coxibes, diclofenac, ibuprofen, ketoprofen, and paracetamol, but also several opioids like codeine, tramadol, and piritramid are used in peroral or intravenous regimes [3]. Furthermore, intraoperative instillation of local anaesthetics and the surgical technique seem to reduce postoperative pain [4]. The classical "cold" dissection with ligatures or punctual bipolar coagulation has been joined in the last few years by "hot" dissecting techniques like radiofrequency, laser, diathermy, ultrasound and coblation settings. However, none of these techniques has shown any superiority to the cold steel dissection, especially when comparing the overall rate of postoperative haemorrhage and pain [5-7]. Andrea M. emphasized 1993 that the use of magnifying devices like microscopes or magnifying glasses allows precise vision and coagulation of vessels during surgery and therefore reduces postoperative bleeding [8,9]. Furthermore, precise coagulation with less collateral damage seems to reduce postoperative pain and intraoperative bleeding, too [9]. Unfortunately in our own study we found no difference in postoperative pain in 48 patients when using magnifying devices for tonsillectomy [10]. To overcome the problem of individual pain sensation, we performed tonsillectomy on one side using a microscope or magnifying glasses whereas the opposite side was operated with the *naked* eyes, thus following an intraindividual design. After surgery, the patients were asked about postoperative pain specifically on the left against the right side. Although there was no statistical significant difference between the methods concerning pain and hemorrhage, the use of magnifying devices, especially a microscope with camera or spy opens new ways of surgical education and exact preparation in the tonsillar capsule. However, most university clinics and educational hospitals still teach the cold steel tonsillectomy

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just with head lights and without any magnification device. A possible reason for this could be the relatively high effort to engage any microscope in the OR and the additional workload for the trainee when dealing with another medical device. To quantify the psychological and physiological effort to engage, the ergonomics and the additional workload when using a microscope or magnifying glasses for tonsillectomy in surgical training the following clinical trial was conducted.

Materials and Methods

N=4 surgeons (3 male, 1 female, in average = 27years old with standard deviation (SD) of 1.4years) in training operated on 48 patients who underwent elective tonsillectomy because of recurrent tonsillitis. The inclusion criteria for the surgeons was a comparable level of experience in tonsillectomy: all four were at the beginning of their surgical training and had no experience in tonsil surgery. All tonsillectomies were performed under general anaesthesia by cold dissection with punctual coagulation using a bipolar forceps when necessary. According to the local Ethic Committee approval and the declaration of Helsinki every surgeon and patient signed informed consent which could be revoked at each time without justification. Criteria for exclusion from the study were: age younger than 6 years, mental disorders, unilateral tonsillectomy, abscess or tumour of the tonsils, pregnancy, anamnestic regular taking of analgetics or anticoagulants, combination with other surgical procedures (except adenotomy and tympanostomy with or without positioning ventilation tubes). All surgeries were done at the ENT department of the University of Munich in the timespan from 07/13/2011 to 08/24/2012.

Every subject (surgeon) had to operate on 12 patients, which means dissecting 24 tonsils with and without magnifying devices. Patients were randomized into three treatment groups according to the used magnifying device. Tonsillectomy was either performed with the *naked* eyes and headlamp, or using magnifying glasses (SuperVu Galilean, magnification 2.5 with headlamp, *Rudolf Riester GmbH, Jungingen, Deutschland*), or using a microscope (OPMI 9, focus 30 cm, magnification 1.6, *Carl Zeiss AG, Jena, Deutschland*). To avoid interference with the surgeon's handedness, the patients in each group were further randomized into two groups so that half of the surgical techniques were performed either on the patient's right or on his left side.During the operation and 5 minutes before and afterwards the surgeons were connected to a biofeedback device (NeXus 10, Mindmedia, NL), in order to monitor the breathing frequency, heart frequency (HF), the heart rate variability (HRV) and the masseter tone continuously. Start and end of each tonsillectomy were marked by a manual trigger of the biofeedback device.

In the spectral analysis of the HRV three frequency bands are important:

Very Low Frequency: 0.02-0.06 Hz

Low Frequency: 0.07-0.14 Hz

High Frequency: 0.15-0.40 Hz

A temperature component is included in the low frequency band, the blood pressure component is included in the 0,1 Hz frequency (low frequency band) and the respiratory component is in the high frequency band.

In exhausting mental activity the heart beat becomes more regular to ensure a continuous oxygen supply of the brain. The same procedure can be observed by physical effort. The higher the mental or physical effort of the test person, the lower is the variability of the heartbeat, which means the more regular the heart beats. Thereby, the deviations of the mean interbeat intervals get smaller. This way it can be measured how exhausting the mental workload for an organism is. All three frequencies show a suppression of the HRV by exertion and concentration [11], but the biggest difference is seen in the low frequency band, especially by the 0,1 Hz component [12,13]. The HRV was monitored during the whole operation and five minutes before and afterwards continuously. This way a calibration with rest situations was given. The spectral analysis of the interbeat intervalls have been implemented with the program BIOTRACE+ (developed by MindMedia in NL). With this spectral analysis it is possible to make a differentiation of the three frequency bands listed above and to quantificate them. BIOTRACE uses the siscrete fourier analysis to split the time series into spectra.

As an additional indicator of physical and mental effort the masseter tonus was measured, too [14]. In situations of high tension a significantly higher masseter tone is measurable through the unconscious contraction of the muscles by biting on the jaws.

Figure 1 – The three different study groups with the monitored surgeons.

After every operation, each surgeon filled out the first twelve questions of a standardised and validated questionnaire the *Human Factors Evaluation Questionnaire for Computer Assisted Surgery Systems* (HFEQ-CASS) [15]. The HFEQ-CASS was designed by the technical group for Industrial, Engineering and Organisational Psychology at the TU Berlin and the Innovation Centre Computer Assisted Surgery (ICCAS) Leipzig especially for evaluating cognitive load in using medical devices in ORs. The HFEQ-CASS records 38 items in two categories. The first question block consisted of 12 questions to:

Mental demands and workload (5 questions),

Surgical results of the operation (1 question),

Situation awareness (3 questions),

Speed (1 question),

Readiness to take risks (2 questions).

Each question was comparing the magnifying device to the „gold standard "with head lamp. The first five questions were obtained from the NasaTLX questionnaire [16]. The concept and questions on situation awareness were developed by M.R. Endsley in 1999 [17]. Workload, situation awareness

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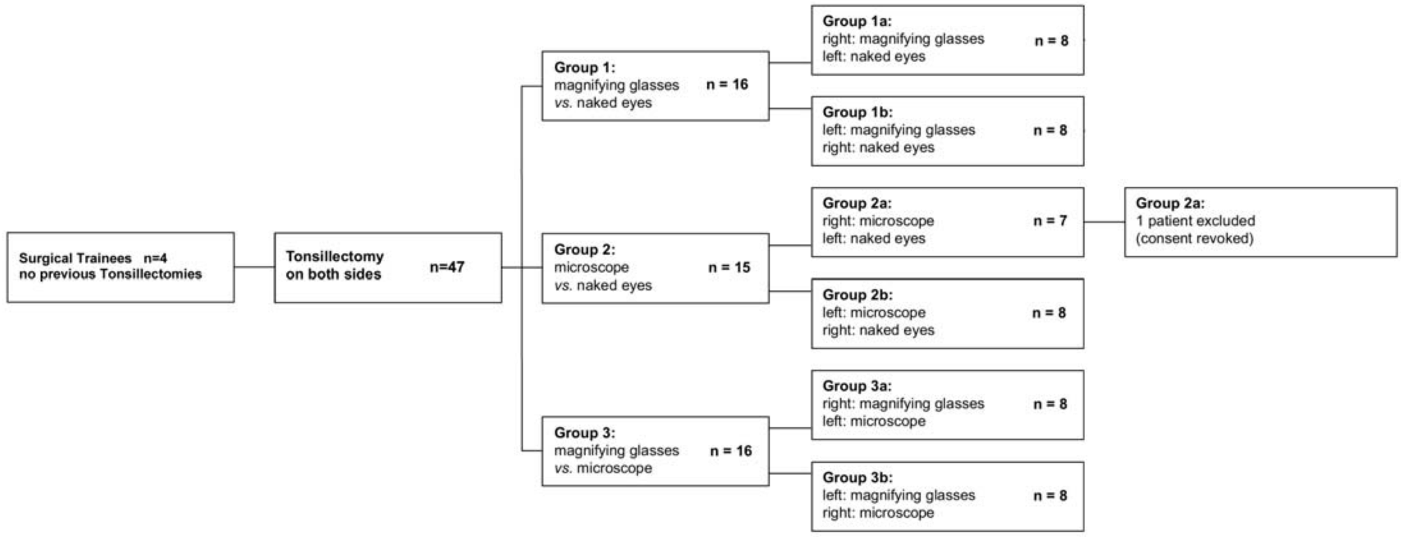

Figure 1: The three different study groups with the monitored surgeons.

and perceived risk can be more, less or similar to the gold standard with naked eyes. The HFEQ-CASS asks the subject to give mark between 1 and 5 for the specific workload, whereas 3 means the workload is similar, 1-2 means the workload is more and 4-5 means the workload is less with a magnifying device. A check of internal consistency (Cronbach's α) was possible on the basis of the redundant method of enquiry and produced conclusions on the reliability of the questionnaire. In preliminary investigations on 213 surgeons, Cronbachr's α produced between 0.69 and 0.83 (whereby >0.7 values are considered very reliable) [18].

Statistics

Each surgeon performed 8 tonsillectomies with another magnifying device or just the head lamp. In total 96 tonsils were removed. The following objective parameters were statistically evaluated:

1. Heartrate [b/min]

2. Heart rate variability [$(b/min)^2$/sec]

3. Respiratory frequency [r/min]

4. Masseter tone

5. Time needed for the operation for each site [minutes]

7. HFEQ-CASS [1-5, deviation from the midline 3]

The statistical evaluation was performed with an analysis of variance (ANOVA) for repeated measurements. The program used was IBM SPSS Statistics 21. A significance was considered if $p < 0.05$.

The study design was in compliance with the declaration of Helsinki and the CONSORT statement 2010 and was approved by the ethics committee of the medical faculty.

Results

47 of the originally 48 randomized operations were finally included in the study because one patient exercised his right to revoke his consent (Figure 2 - Tree diagram of the randomised treatment groups according to the CONSORT statement). Mean age of the patients was 25years; 10 patients were above the age of 18. The male-female proportion was 18:27.

The main outcome measure was to quantify the mental workload of using magnification devices in tonsillectomy compared to the "gold standard" just with the headlamp.

(Figure 3 – Heartrate and heartrate variability pre-, intra- and postoperatively in the different study groups with mean values and standard deviation in brackets, * shows statistical significant difference (p<0.05) compared to the baseline in Chi-square test).

(Figure 4 – Masseter tone and respiratory frequency in the different study groups with mean values and standard deviation in brackets. There was no statistical significant difference in the study groups compared to the baseline before and after surgery in Chi-square test).

There is a statistical significant difference in the heartrate and heartrate variability when using the microscope compared to the baseline before and after surgery (p=0.023) using the Chi-square test for pairwise comparison between the study group and the baseline value. Whereas the naked eyes (p=0.089) and the magnifying glasses (p=0.077) showed no statistical difference in the heartrate and heartrate variability compared to the baseline This means the mental demand for the trainee is higher when operating a microscope in tonsillectomy. The respiration rate and masseter tone showed no statistical significant differences in the naked eyes group (p=0,12), the magnifying group (p=0.16) and the microscope group (p=0.097) using the Chi-square test.

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The subjective questioning postoperatively shows a similar picture. The perceived mental demand and the time effort was higher when using the microscope compared to the naked eyes. Whereas the readiness to take risks and the situation awareness felt better with the microscope (Figure 5: Questionnaire comparing the ergonomics of the microscope vs. naked eyes. Boxplot shows standard deviation in the grey box, 95% confidence interval in whiskers and the outliers as dots, significance niveau of p=0.05 is reached if the whiskers dos not touch the midline (red line)).

Comparing the magnification glasses to the naked eyes there was no subjective difference in the mental demand, but in the better situation awareness and in the risk profile. Only the time effort (surgical speed) felt worse with the magnifying glasses. (Figure 6: Questionnaire comparing the ergonomics of the magnifying glasses vs. naked eyes. Boxplot shows standard deviation in the grey box, 95% confidence interval in whiskers and the outliers as dots,, ignificance niveau of p=0.05 is reached if the whiskers do not touch the midline (red line)).

Figure 2: Tree diagram of the different treatment groups baccording to the CONSORT statement.

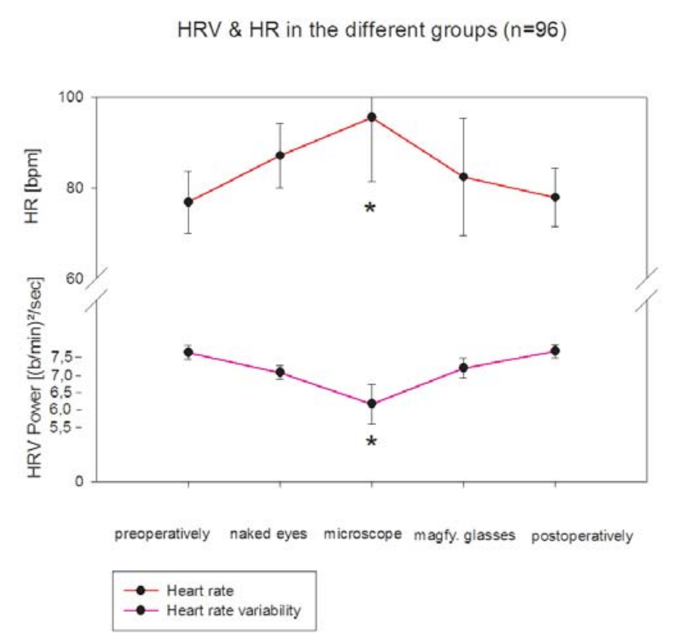

Figure 3: Heartrate and heartrate variability pre-, intra- and postoperatively in the different study groups with mean values and standard deviation in brackets, * shows statistical significant difference (p<0.05) compared to the baseline in Chi-square test.

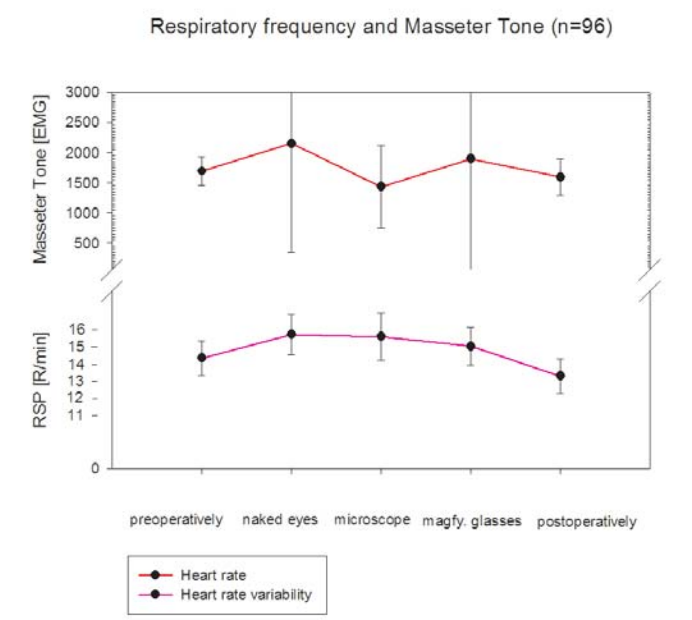

Figure 4: Masseter tone and respiratory frequency in the different study groups with mean values and standard deviation in brackets. There was no statistical significant difference in the study groups compared to the baseline before and after surgery in Chi-square test.

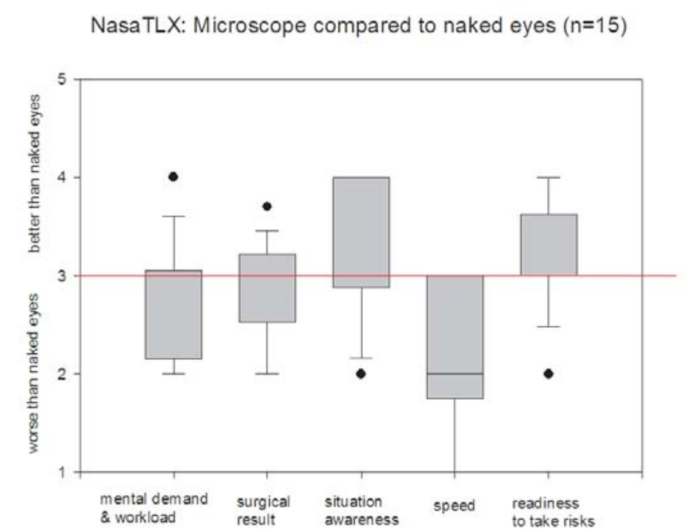

Figure 5: Questionnaire comparing the ergonomics of the microscope vs. naked eyes. Boxplot shows standard deviation in the grey box, 95% confidence interval in whiskers and the outliers as dots. Significance niveau of p=0.05 is reached if the whiskers dos not touch the midline (red line).

Another outcome parameter for the effort to engage was the OR time.

Mean operation time for the side which was operated with magnification devices (i.e. the microscope) was slightly longer. However, this comparison did not reach statistical significance (Figure 7 – Duration of tonsillectomy in minutes [min] as boxplots with mean values, standard deviation in the grey box, 95% confidence interval in whiskers and the outliers as dots, Wilcoxon test documented no significant difference between the treatment groups (p = 0.07)).

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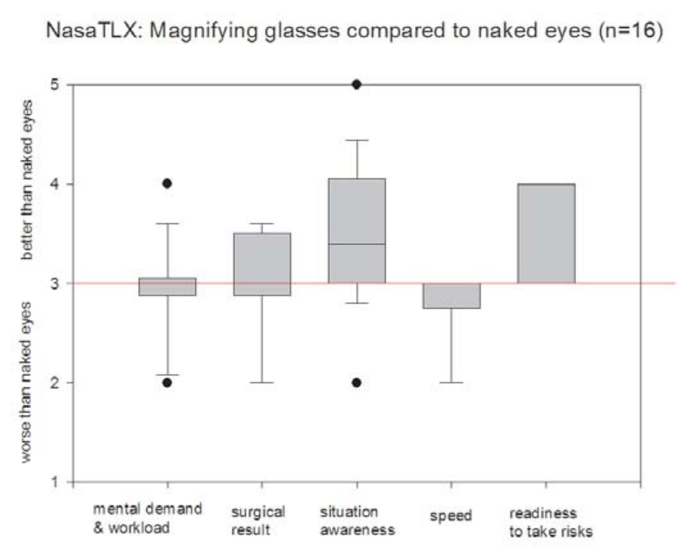

Figure 6: Questionnaire comparing the ergonomics of the magnifying glasses vs. naked eyes. Boxplot shows standard deviation in the grey box, 95% confidence interval in whiskers and the outliers as dots, Significance niveau of p=0.05 is reached if the whiskers do not touch the midline (red line).

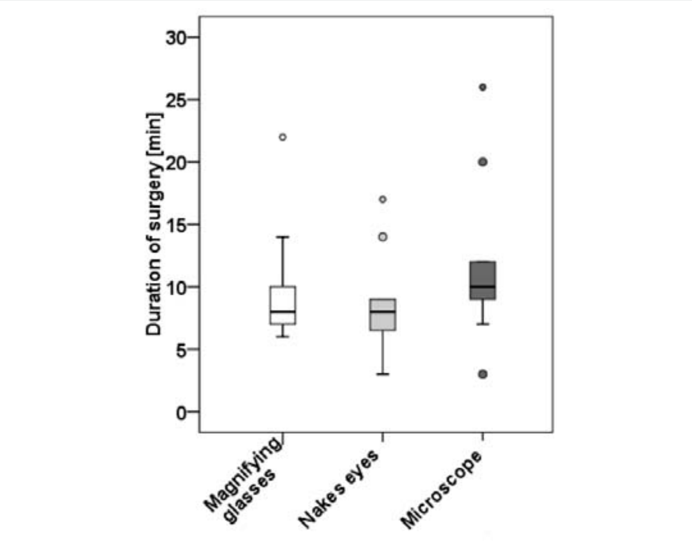

Figure 7: Duration of tonsillectomy in minutes [min] as boxplots with mean values, standard deviation in the grey box, 95% confidence interval in whiskers and the outliers as dots, Wilcoxon test documented no significant difference between the treatment groups (p = 0.07).

Discussion

Preparation of the tonsils with a magnifying device seems very logical. The surgeon has better vision of feeding vessels, more exact preparation at the capsule and holds the perfect distance to the oral cavity [9]. Most of the experienced surgeons are using magnifying devices, i.e. loups, for almost every surgical procedure [19]. Tonsillectomy, as Class I (easiest) procedure, is one of the initial procedures in surgical training of head and neck surgery. Maybe that is why the tonsillectomy is so often done by beginners with young sharp eyes, who do not have own loupes or are not used to it. In contrast, almost every OR owns a microscope with or without spy or video-output. For a better vision of the surgeon and for teaching purposes it makes obviously sense to use such a microscope[9] if not for the effort to engage. Two additional efforts play a role: the additional time effort of mounting the microscope (plug in, draping, plug out) and the additional mental workload when dealing with a high end medical device. The preparation of the microscope is normally done by the OR Team before or during the patient enters the OR, therefore it should not play a distinctive role in OR time management. Whereas operating a complex binocular microscope with fixed focus and heavy lenses could be such a big mental effort for the surgeon and his supervisor, that most of the clinics worldwide do not use such a device for surgical training of tonsillectomy [20]. Handling the additional information from the microscope creates a specific mental workload. Dealing with this workload during tonsillectomy differs from surgeon to surgeon. Our goal was to evaluate the subjective and objective effort of magnification devices in surgical beginners (no previous tonsillectomies done). Subjective data was collected by a simple questionnaire: the HFEQ-CASS. This standardized and validated questionnaire is specially designed for the workload evaluation of surgical devices [21,22]. Objective data was collected by the time measurement and the biometrical data of the surgeon.

In modern industrial engineering the ergonomics of every new assistance system (i.e. navigation systems or visualization systems) is tested many times before it comes to the market. However, only a few working groups are investigating the interaction during surgical procedures between complex automation or visualization systems and human factors [23-29]. This is despite the fact that surgical visualization systems and assistance systems become more prevalent and more complex. Many studies use the HRV as an indicator for mental effort but the evaluations of the results vary a lot [30,31]. There are no standard guidelines for the evaluation of the HRV. The critical point is that there are many activities which cause mental load and there is no measurement for quantification [30]. The only way is to indirectly conclude the mental load from some parameters: like the HR, HRV and/or masseter tone [32,33].

The measurements of this trial show that a state of mental load dominates in surgical interventions. Preoperative the HRV is high, during the operation the HRV decreases and is suppressed. After the operation the HRV increases again. When using the microscope the HRV was significantly suppressed compared to the baseline s. A similar picture can be observed with the analysis of the heart rate (HR). The HR is increased during the operation compared to the baselines. A significant difference could be monitored when using the microscope compared to the baseline. Therefore, the mental load in tonsillectomy with a microscope is higher for beginners compared to the standard operation with naked eyes and a headlamp with or without magnifying glasses. Every surgeon did 8 tonsillectomies with the microscope. However, if only the last two microscope tonsillectomies would have been evaluated, there would be no statistical difference. Whether this is due to the small sample size or the learning curve remains unclear which is clearly a limitation of the study.

A similar result could be concluded from the masseter tone monitor and the respiratory frequency. But this data shows

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another limitation of the study, because it is not reliable due to the fact, that breathing and the masseter tone rise just when surgeons look through a microscope and rest their eyes on the oculars. This is because of the relatively fixed head state and the immobilization of the jaw

Regarding the subjective data of the questioning, the results fits together: the perceived mental workload was highest when operating a microscope and only slightly higher when looking through magnification glasses. Although the trainee surgeons thought that the time effort is negative when using a microscope, OR time did not reach significant thresholds. The microscope procedure took a little longer in the beginning but with no significance to the other study arms.

Taken together, the results of the present study suggests that the mental distress is higher when operating a microscope for tonsillectomy in the first eight times. Despite the many advantages of an OR-microscope, this may hinder the usability of such devices for this procedure for beginners.

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