Evaluation of response variables in computer-simulated virtual cataract surgery

Per Söderberg*[a,b,cNF], Carl-Gustaf Laurell[aF], Wamidh Simawi[a,cNF], Per Nordqvist[dF], Eva Skarman[dF], Leif Nordh[dF]
[a]St. Erik's Eye Hospital, Karolinska Institutet
[b]Dept. of Biomedical Engineering, University of Miami
[c]Dept of Ophthalmology, Mälarsjukhuset Eskilstuna
[d]Melerit AB

ABSTRACT

We have developed a virtual reality (VR) simulator for phacoemulsification (phaco) surgery. The current work aimed at evaluating the precision in the estimation of response variables identified for measurement of the performance of VR phaco surgery. We identified 31 response variables measuring; the overall procedure, the foot pedal technique, the phacoemulsification technique, erroneous manipulation, and damage to ocular structures. Totally, 8 medical or optometry students with a good knowledge of ocular anatomy and physiology but naive to cataract surgery performed three sessions each of VR Phaco surgery. For measurement, the surgical procedure was divided into a sculpting phase and an evacuation phase. The 31 response variables were measured for each phase in all three sessions. The variance components for individuals and iterations of sessions within individuals were estimated with an analysis of variance assuming a hierarchal model. The consequences of estimated variabilities for sample size requirements were determined. It was found that generally there was more variability for iterated sessions within individuals for measurements of the sculpting phase than for measurements of the evacuation phase. This resulted in larger required sample sizes for detection of difference between independent groups or change within group, for the sculpting phase as compared to for the evacuation phase. It is concluded that several of the identified response variables can be measured with sufficient precision for evaluation of VR phaco surgery.

Keywords: cataract surgery, phacoemulsification, simulator, response variables

1. INTRODUCTION

The present work aimed at evaluating a number of response variables identified for evaluation of the performance during a virtual reality phacoemulsification procedure.

In modern societies phacoemulsification cataract surgery (phaco) is the most common surgical procedure with an incidence approaching 1/100 inhabitants/yr. The incidence of cataract surgery is expected to increase substantially due to a quickly increasing population age in countries in development.

Modern phaco usually consists of a less than 3 mm incision into the eye in the periphery of the cornea, opening of the crystalline lens by tearing an operculum in the anterior lens capsule, capsulorhexis, mobilization of the lens nucleus by liquid dissection along the lens capsule, ultrasound emulsification and simultaneous aspiration of the nucleus, aspiration of the cortical material and implantation of an artificial intraocular lens into the empty capsule. The success of the operation is related to the maintenance of an intact capsular bag.

Despite extensive teacher intensive training, surgeons in training have reported an incidence of 5-20 % of capsular ruptures during their first 200 cases [1-4]. These figures are similar for experienced surgeons [5, 6]. Studies of experienced surgeons have shown that the number of complications decreased exponentially reaching the asymptote after 400 [7] and 1000 cases respectively [8].

Recent development of personal computers have made it possible to simulate virtual reality with relatively inexpensive computers. It has been demonstrated that virtual reality training leads to faster adaptation to the psychomotor restrictions encountered by laparoscopic surgeons [9].

*per.soderberg@ste.ki.se; +46 8 672 3098; fax +46 8 318447; http://www.ste.ki.se; St. Erik's Eye Hospital, SE 112 82 STOCKHOLM, SWEDEN. NF: No financial interest.

We have developed a virtual reality phaco simulator [10-13]. The simulator consists a personal computer, simulation software and a surgeon interface. A preliminary clinical evaluation indicated that the simulator authentically simulates cataract surgery [14]. This was indicated by the fact that an experienced surgeon performed better than novices as measured by some preliminary selected response variables.

The aim of the current study was to determined the sources of variation and their magnitude in thirty one response variables identified for measurement of performance of VR phaco. The consequences of the variability's, for use of the identified response variables as efficient measures of the performance during the simulation, was analyzed.

1 METHODS

1.1 The simulator

The simulator (PhacoVision®, Melerit AB, Sweden) consists of a personal computer, simulation software and hardware interfaces.

The simulation software is based on a generalized simulation software (M-base®, Melerit AB, Sweden) working on top of Cosmo 3D/Optimizer (Silicon Graphics Inc., USA). M-base has been used to write the phacoemulsification procedure.

The hardware interfaces provide input from the trainee to the software and feed back visual output from the software to the trainee. The trainee input interface consists of a phacoemulsification hand piece and a nuclear manipulator hand piece, both mounted with four degrees of freedom (three space dimensions and rotation), a microscope foot pedal controlling x and y-direction and focusing in the field and zoom, and a one dimensional phacoemulsification pedal that controls irrigation, aspiration and phaco-power depending on the pedal position. The trainee receives three dimensional visual feed back of the surgical field in real time presented on two organic light-emitting diode (OLED) displays.

During the measurement session the patient case was adjusted as indicated in Table 1

Table 1 VR parameters

Parameter	Setting
1 Patient movement	
1.1 Average frequency of x-y patient field drift calculated for no drift period	1 Hz
1.2 Maximum velocity for x-y patient field drift	2 mm/s
1.3 Maximum x-y patient field drift, 4 mm	4 mm
2 Pupillary parameters	
2.1 Pupillary diameter	7 mm
3 Lens Parameters	
3.1 Maximum allowed stretching of the zonuale before lost lens	1.5 mm
3.2 Maximum allowed zonular load	1 rel
3.3 Nucleus hardness	0.5 rel.
3.4 Nuclear translational movement per translational force	1 mm/rel. force
3.5 Force required to produce cracking	1 rel.
4 Phacoemulsification instrument related	
In frontal plane counter-clockwise angle between 12 a' clock and phacoemulsification handle axis	10 deg
In frontal plane counter-clockwise angle between 12 a' clock and manipulator handle axis	290 deg
Distance tip-irrigation port center	2 mm
Average incidence of occurrence of bubbles	1 Hz
Average number of bubbles per group	4 /group

1.2 Experimental design

The population studied was defined as undergraduate medical and optometry students with a good knowledge about ocular anatomy and physiology but naive to cataract surgery.

A sample of the population was selected consecutively from class lists of students 2005 at the Karolinska Institutet. Students that accepted to participate in the study without any remuneration were recruited. All subjects recruited were primarily included. All subjects primarily included took a tutorial course consisting of; watching a standard edited video of a regular phacoemulsification cataract surgery, watching an instruction video for PhacoVision®, demonstration of PhacoVision® by an experienced administrator, watching a demonstration operation by the experienced administrator, and performing five learning sessions. If at least one of the learning sessions was completed without breakage of the posterior capsule, the subject was kept included in the study, else excluded.

Totally, 31 response variables were identified and measured during the simulations. The response variables belonged to five main categories (Table 2)

Table 2 Response variables

Variables description	Number within cathegroy
1 Overall procedure	
1.1 Procedure time consumption	2
1.2 Energy deposited	1
2 Foot pedal technique	9
3 Phacoemulsification technique	
3.1 Phaco tip movement	4
3.2 Manipulator tip movement	4
4 Erroneous manipulation	6
5 Damage to ocular structures	5
Σ	31

The experimental design is outlined in (Figure 1).

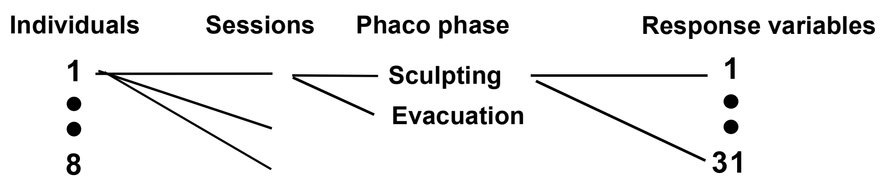

Figure 1 Experimental design

Altogether, 8 subjects performed VR phaco surgery. Each subject performed three sessions. Each session was divided into a sculpting phase and an evacuation phase. For each phase all 31 response variables were measured.

2 RESULTS

The measured data for each of the response variables was analyzed with analyzes of variance according to a hierarchal model (Equation 1).

Equation 1 $$x_{ij} = \mu + A_i + \varepsilon_{j(i)}$$

Here, μ is the population mean, A_i is a term for the variation among individuals (j=1..8), and $\varepsilon_{j(i)}$ is a term for the variation among sessions within individuals (k=1..3). The analysis of variance provided estimates of the variance for individuals, $\hat{\sigma}_A^2$ (s_A^2), and for the variance of sessions within individuals $\hat{\sigma}_\varepsilon^2$ (s_ε^2).

The sum of these variance estimates was considered as the total variance for VR simulations considering one session for one individual. The fraction of each of them was calculated as the estimated variance divided by the total.

For the sculpting phase of the VR phaco, the variation among sessions within individuals was large in relation to the variation among individuals for most of the response variables evaluated (Figure 2).

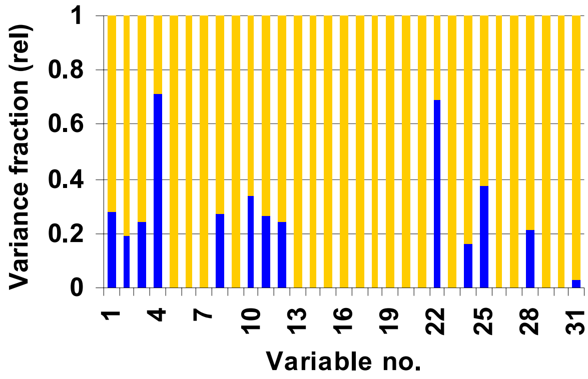

Figure 2 Sculpting. Fraction of variance for sessions within individuals (light grey part of bar) and fraction of variance for individuals (dark grey part of bar).

For the evacuation phase, data sets from 3 individuals were missing. The estimation of the variance components was therefore based on a reduced sample size of 5. For the evacuation phase, the variation within individuals was smaller in relation to the variation among individuals compared to what was found for the sculpting phase (Figure 3).

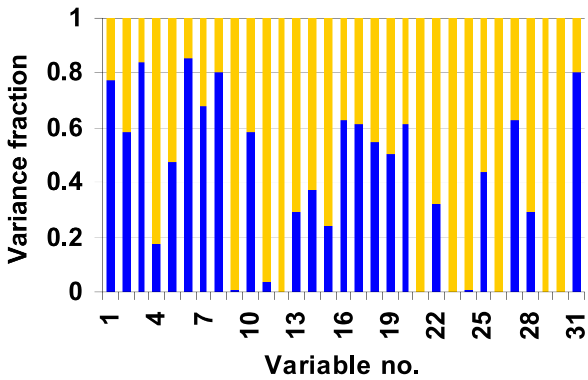

Figure 3 Sculpting. Fraction of variance for sessions within individual (light grey part of bar) and fraction of variance for individuals (dark grey part of bar).

The variance estimates obtained in the analysis of variance based on Equation 1 can be used to estimate the variance for various experimental designs.

2.1 Sample size for between independent groups comparison

The variance for individuals, s_x^2 , considering the estimate of an individual as the average of n sessions, can be estimated as indicated by Equation 2.

Equation 2 $$s_x^2 = s_A^2 + \frac{s_\varepsilon^2}{n}$$

Using the estimate of the variance for individuals, s_A^2, and the estimate of the variance for sessions within individuals, s_ε^2, as obtained from the analysis of variance, the sample size required to detect a minimum significant difference of 20 % between an experimental group and a control group, was calculated considering an α-error of 0.05, a β-error of 0.2, and 3 sessions [15].

2.2 Sample size for within a group comparison

Within a group comparison is applicable e.g. for measurement of improvement. The variance for within a group comparison, s_d^2, considering the estimate of an individual as the mean difference of n sessions, can be estimated as indicated by Equation 3.

Equation 3 $$s_d^2 = 2\frac{s_\varepsilon^2}{n}$$

Using the estimate of the variance for sessions within individuals, s_ε^2, as obtained from the analysis of variance, the sample size required to detect a minimum significant difference of 20 % between an experimental group and a control group, was calculated considering an α-error of 0.05, a β-error of 0.2, and 3 sessions [15].

For the sculpting phase it was found that fairly large sample sizes are needed for between group comparison as well as for within group comparison (Figure 4).

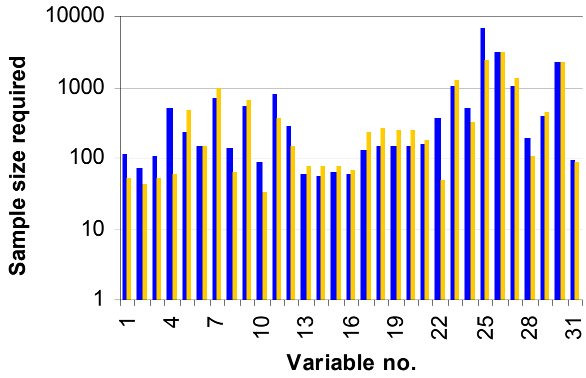

Figure 4 Sculpting. Sample sizes required versus response variable number, to detect a minimum significant difference of 20 % with an α-error of 0.05, a β-error of 0.2, and 3 iterations of sessions for between independent groups comparison (dark bars) and within group comparison (grey bars).

The most precise response variables for the sculpting phase are listed in Table 3.

Table 3 Sculpting, sample size required for the most precise response variables

Response variable	Sample size required	
	Independent group design	Within group design
SculptingTime (s)	73	43
PhacoEnergyUsed (rel.)		54
OffInFocusTime (s)		59
AspIrrInFocusTime (s)		64
SculptingInFocusTime (s)		34
PhacoPathTotal (mm)	60	75
PhacoPathX (mm)	58	
PhacoPathY (mm)	65	
PhacoPathZ (mm)	58	68
NoIrrigationTime (s)		49

These were selected on the assumption that an acceptable sample size is less than or equal to 75, considering the above selected criteria for minimum significant difference and probability for wrong conclusion in the statistical inference.

For the evacuation, phase smaller sample sizes are required for detection of a similar minimal significant difference with the same criteria for wrong conclusions in the statistical inference (Figure 5).

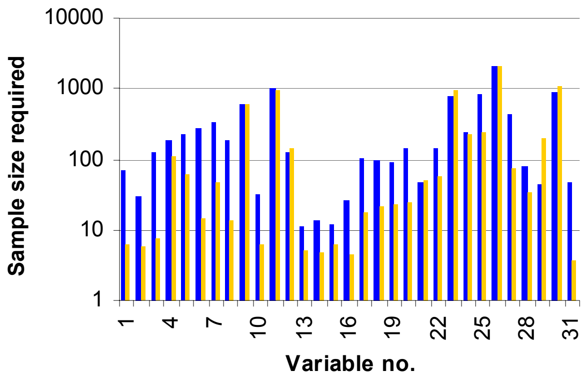

Figure 5 Evacuation. Sample sizes required versus response variable number, to detect a minimum significant difference of 20 % with an α-error of 0.05, a β-error of 0.2, and 3 iterations of sessions for between independent groups comparison (dark bars) and within group comparison (grey bars).

The most precise response variables for the evacuation phase are listed in Table 4.

Table 4 Evacuation, sample size required for the most precise response variables

Response variable	Sample size required	
	Independent group design	Within group design
TotalProcedureTime (s)		6
EvacuationTime (s)		6
PhacoEnergyUsed (rel.)		8
IrrInFocusTime (s)		15
AspIrrInFocusTime (s)		14
EvacuationInFocusTime (s)		6
PhacoPathTotal (mm)	11	5
PhacoPathX (mm)	14	5
PhacoPathY (mm)	12	6
PhacoPathZ (mm)	27	4
ManipulatorPathTotal (mm)		18
ManipulatorPathX (mm)		21
ManipulatorPathY (mm)		22
ManipulatorPathZ (mm)		25
ZonulaStretch (mm)		4

These were selected on the assumption that an acceptable sample size is less than 30, considering the above selected criteria for minimum significant difference and probability for wrong conclusion in the statistical inference.

3 DISCUSSION

The purpose of the current study was to evaluate the precision of identified response variables for measurement of performance during VR phaco with PhacoVision®.

The relatively small sample size in the current pilot study limits the precision in the estimates and a larger sample size is desirable. The current estimates are however believed to be good indicators of the precision.

The current experimental design produces multivariate data on several response variables in one sample. Therefore, only the first estimates of variance components represent a statistically independent estimate. All subsequent estimates are dependent with all the previous estimates from the same sample. The purpose of the current study was however to estimate the magnitude of the variance components for the identified response variables rather than to make statistically correct estimations.

The fact that during the sculpting phase, the variation among sessions within individual is fairly large in relation to the variation among individuals for all the identified response variables (Figure 2) is reflected in the fairly large sample sizes required to detect a 20 % change (Figure 4, Table 3). For both independent and within group design, the variation among individuals may be reduced by increasing the number of sessions per individual. This is however time consuming if large clinical evaluations are made.

The finding that during the evacuation phase, the variation among sessions within individual was comparable to the variation among individuals (Figure 3) is reflected in much smaller sample sizes required to detect a 20 % change (Figure 5, Table 4). This holds both for independent and within group design. Several of the response variables identified are associated with enough precision to be able to detect reasonably small changes with adequate sample sizes and relevant risks for wrong conclusion at statistical inference.

The current data indicate that it is useful to analyze the performance during VR phaco separately for the sculpting and the evacuation phase.

We have developed a VR phaco simulator [10-14]. The current study demonstrates that some of the response variables that we have identified for measurement of the performance during the simulation have enough precision to be useful in clinical evaluations.

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