Dynamic Intraocular Pressure Measurements During Vitrectomy

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Objectives: To directly measure dynamic intraocular pressure (IOP) during vitrectomy and to determine whether disposable pressure transducers placed in the infusion line can indirectly measure with accuracy the dynamic IOP during vitrectomy.

Methods: Experimental clinical study of 10 patients undergoing vitrectomy. Dynamic IOP was sampled via an extra pars plana incision with a catheter transducer equipped to measure direct IOP during vitrectomy by attaching a metal flange near the pressure-sensing tip. Disposable blood pressure transducers were placed in the infusion tubing fluid path to determine the IOP by indirect means. During various maneuvers of vitrectomy including air-fluid exchange and gas-forced infusion, pressure measurements were taken simultaneously from the indwelling pressure transducer and the disposable blood pressure sensors in the infusion line.

Results: The directly measured IOP varied between 0 and 120 mm Hg during vitrectomy. During fluid flow, the indirectly measured IOP, calculated from the infusion line pressures, accurately corresponded with the directly measured IOP.

Conclusions: Closed vitrectomy causes wide fluctuations in IOP. The IOP can be accurately measured during fluid flow with inline sensors.

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Closed intraocular surgery with fluid infusion has long been recognized to induce substantial fluctuations in intraocular pressure (IOP). The association between IOP fluctuations, resultant decreased vascular perfusion pressure, and compromised blood flow to the optic nerve and retina has been established. With the intent of reducing complications such as expulsive choroidal hemorrhage and retinal and choroidal ischemia, cataract surgeons have measured fluctuations in IOP during phacoemulsification and extra-capsular cataract extraction.

Wide fluctuations in IOP have also been documented during vitrectomy in animal models, with IOPs fluctuating up to 40 mm Hg in 90 seconds of surgery. Acute IOP elevations block retrograde transport of brain-derived neurotrophic factor through retinal axons and may thus impede the delivery of essential neurotrophins from the brain to the retina. These observations raise the possibility that IOP fluctuations during vitrectomy may have adverse effects on retinal and optic nerve function and visual acuity recovery. Rapidly fluctuating IOP could have adverse effects on visual outcome, especially for patients with compromised retinal or optic nerve blood flow and decreased ocular perfusion pressure. Ocular blood flow in patients with diabetic retinopathy is significantly decreased after vitrectomy, and this decreased perfusion could be one factor that contributes to the variable functional outcome that is reported with vitrectomy. Despite the fact that the Doppler ocular pulsatile technique used for clinical studies has been shown to be somewhat inaccurate in the face of changes in systemic blood pressure, the overall importance of the effect of IOP fluctuations on ocular blood flow cannot be ignored. These reports demonstrate the need for improved determination and control of real-time IOP changes during vitrectomy, similar to previous observations during scleral buckling.

We report a clinical study in which the IOP was measured directly during the vitrectomy procedure by inserting a catheter pressure transducer into the vitreous. We also developed an alternative and less invasive method of monitoring the IOP during vitrectomy by placing blood pres-
sure transducers in the infusion line tubing. This report describes the accuracy of the indirect technique compared with the directly measured IOP.

PATIENT SELECTION

The 10 patients, all older than 18 years, were undergoing vitrectomy for macular hole or preretinal membrane. Exclusion criteria were the presence of glaucoma, diabetic retinopathy, or any retinal vascular disease. Informed consent included permission to make an extra pars plana incision for the purpose of inserting the catheter pressure transducer. This study was approved by the Ophthalmic Devices division of the Food and Drug Administration (FDA), Rockville, Md, and the institutional review boards of St Luke’s Episcopal Hospital, Houston, Tex, and Penn State Milton S. Hershey Medical Center, Hershey, Pa.

CATHETER TRANSDUCER

Standard pressure measurement technology established in pediatric cardiology was modified for vitrectomy. The SP-330 pressure transducer (Millar Instruments Inc, Houston Tex) is a miniature strain gauge device that measures 1 mm in diameter, the size of a 19-gauge needle (Figure 1). The transducer was sterilized with ethylene oxide because steam or other methods of sterilization destroy the delicate strain gauge. The standardized sensitivity is 5 μV/V per millimeter of mercury and the pressure range is −50 to 300 mm Hg. The input and output impedance is standardized at 1000 Ω; the frequency response is linear to 10 KHz. Modification for vitrectomy was achieved by gluing a scleral flange (Synergetics, Inc, St Charles, Mo) 4.6 mm from the tip to provide a secure anchor during surgery. The distance of 4.6 mm from the tip of the catheter to the flange was selected to avoid trauma to the lens (Figure 1).

DISPOSABLE TRANSDUCER IOP PACK

The Edwards TruWave Disposable Pressure Transducer (Edwards Lifesciences, Irvine, Calif) (Figure 2) is standard equipment for inline blood pressure monitoring in critical care units of hospitals. This unit uses silicon-embedded strain gauge microcircuitry and was placed in direct contact with the flowing fluid. The operating range is from −50 to 300 mm Hg; dimensions are 3 cm × 3 cm; accuracy and reproducibility are ±1 mm Hg; and drift is ±0.3 mm Hg. In our surgical device, 2 identical transducers were connected by 2 m of polyvinyl tubing similar to that used for vitrectomy infusion. The plastic casings of the transducers were glued together, back to back, while the 2 m of tubing that separated their respective fluid paths were coiled in a bundle to save space. The complete apparatus was sterilized as a disposable IOP pack (specially manufactured to our design by Edwards Lifesciences). This pack was designed for placement between the connector for the bottle tubing and the vitrectomy infusion cannula. Fluid flow took place across both transducers, where line pressure was sampled from each location. Despite the close proximity of the transducers in their surgical pack, one transducer monitored fluid pressures closer to the bottle (upstream) and the other measured pressures near the eye (downstream) (Figure 3). Two meters of tubing were necessary to provide a fluid path of sufficient length between the transducers to ensure reliability of the IOP model. (There exists an “unestablished flow zone”21,22 at the start of the 2 m of tubing. This results in a relation between the pressure drop and the flow rate, which is well modeled by the slightly nonlinear expression: pressure drop = constant × (flow rate)2. In turn, this leads to IOP = constant × (pressure drop)3, which is the IOP model. Technical details concerning this derivation are available on request.)

COMPUTER CONSOLE

A unique computer console was designed and built according to FDA standards to store data transmitted via the 3 pressure transducers used in the clinical trial and to approximate the direct IOP using infusion line pressures. This computer was positioned adjacent to the vitrectomy machine during the cases. Before approval for entry into the operating room, the electronic console was inspected for safety by the biomedical engineering departments of both participating institutions.

DETAILS OF EXPERIMENTAL PROCEDURE

Setup

Accuracy of the catheter transducer was essential for acquiring meaningful IOP data. Before ethylene oxide sterilization, each catheter was calibrated with a water column. The computer console was positioned adjacent to the vitrectomy unit (Millennium; Bausch and Lomb, Rochester, NY, or Accurus surgical system; Alcon Laboratories, Fort Worth, Tex). Connecting electrical cables of 10 ft in length were used to carry pressure signals from the operating field to the console.

Beginning Surgery

Initial preparation of the conjunctiva and globe for vitrectomy proceeded as usual. After the standard infusion cannula was
sutured into place, the IOP pack was placed in the fluid path between the tip of the regular infusion bottle tubing and the disposable 4-mm vitrectomy infusion cannula. The pack was taped to the side of the patient’s face, with the disposable Edwards TruWave blood pressure transducers positioned at eye level. Correct placement of the IOP pack with respect to the patient’s globe was essential for accurate IOP prediction (Figure 4).

After the IOP pack was in proper position and while the catheter transducer was still on the surgical tray, all 3 transducers were zeroed to air pressure for calibration.

Vitrectomy with gravity infusion then proceeded normally as 3 types of pressure readings were recorded in the computer console: direct IOP, upstream infusion line pressure (closer to bottle), and downstream infusion line pressure (closer to infusion cannula). Maneuvers such as pressing on the globe, peeling of preretinal membranes, and air fluid exchange were performed. Toward the end of case 1, the disposable IOP pack was disconnected, the gas-forced infusion pack was set up, and a comparison of direct IOP with the IOP designated on the vitrectomy console was carried out.

Clinical trial follow-up, as required by the FDA, consisted of first postoperative day and seventh postoperative day documentation of lack of retinal or optic nerve damage and absence of infection. No patients had adverse effects such as cataract, vitreous hemorrhage, or retinal tear as a result of this study.

DATA COLLECTION

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FOLLOW-UP

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TECHNICAL CONSIDERATIONS

Laboratory testing was done on the accuracy of the slope milivolt/(millimeters of mercury X millivolt excitation) of both the vitreous transducer sampled direct IOP, the first disposable blood pressure transducer sampled irrigation fluid pressure closer to the bottle, and the second transducer measured fluid pressure closer to the infusion cannula. The extra pars plana incision was made with a 19-gauge microvitrectomy blade.

The transducer entered the globe with the delicate sensing element pointed away from the midvitreous and toward the scleral wall to minimize perturbations caused by fluid currents during surgery. The infusion bottle height varied from 20 to 30 cm above the eye.
disposable and catheter transducers and revealed that the transducers had a slope that was within the manufacturers’ specifications (±1%). To ensure maximum accuracy during this study, our experiments recorded a zero point for all 3 transducers both before and after acquisition of data during surgery.

Exact positioning on the patient’s face of these disposable transducers with relation to the catheter was important for the accuracy of the indirect measurement method. However, under operating room conditions, it was difficult for the surgeon to always place the sterile IOP pack precisely at the draped patient’s eye level so there was a static pressure bias between the disposable and the catheter sensors. This bias, which we named the “static pressure differential,” was calculated from each data set after the acquisition was completed. This constant is the correction for the hydrostatic head between the IOP pack sensors and each patient’s eye.

RESULTS

VISUAL INSPECTION OF IOP DATA

Two data sets are presented: the direct IOP during various maneuvers of vitrectomy and the comparison of the actual IOP with the values indirectly calculated from data supplied by the IOP pack. Representative graphs of IOP vs time data from 2 of the 10 cases are shown in Figures 5, 6, 7, 8, 9, and 10.

Case 1

Direct IOP. A typical tracing of the IOP during 43.5 minutes of vitrectomy for macular hole is shown in Figure 5. When there was no fluid flow and the surgeon was not touching the eye, the direct IOP was determined by the bottle height, which corresponded in this instance to about 40 mm Hg. Spikes higher than that level were caused by the motion of instruments, either inside or outside the globe. Grasping the globe with forceps caused sudden IOP spikes, as did placing sutures and wide rotations of the vitrectomy cutter, with subsequent pressure on the scleral wound. During the aspiration phase of vitrectomy, pressures fluctuated and rapidly decreased to close to 0 mm Hg. The stair-step pressure configuration at the end of the case in Figure 5 corresponds to the IOP measured under gas-forced infu-
sion conditions. Gravity infusion was switched to the gas-forced mode for a brief period while we compared the true IOP to the pressure selected on the vitrectomy console. The true IOP measured at least 10 mm Hg higher than the set point on the machine.

**Indirect IOP.** Comparison of the indirect IOP with the direct IOP appears in Figure 6. The indirect IOP was calculated with the IOP model according to well-known physics principles. The pressure curves are superimposed. Because our device functions only during active fluid flow across the disposable transducers in the infusion line, there is no predicted pressure higher than bottle height. Toward the end of the case shown in Figure 6, the green color of the predicted IOP disappeared after the surgeon switched infusion bottles to test the accuracy of the gas-forced infusion method.

**Expanded View of Indirect IOP.** Figure 7 shows an expanded view of the direct and indirect IOPs during 13.8 minutes (15,000 samples at 18 samples per second) of the surgery depicted in the previous 2 pictures. During fluid flow, the predicted IOP tracked the true IOP with remarkable accuracy.

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**Case 2**

**Direct IOP.** Figure 8 is the IOP tracing of a second vitrectomy for a macular hole case lasting 21 minutes. The IOP ranges between 5 and 120 mm Hg; air-fluid exchange at the end of the case resulted in a stable IOP of 25 mm Hg. This corresponded exactly with the air pressure setting on the console of 25 mm Hg.

**Indirect IOP.** Figure 9 is a comparison of the directly and indirectly measured IOPs. The indirect pressure tracks direct IOP only during fluid flow and will not register greater than the pressure due to bottle height; the IOP spikes greater than the pressure due to bottle height were caused by instruments pressing on the globe.

**Expanded View of Indirect IOP.** Figure 10 shows that during fluid flow, the pressure measurements derived from infusion line readings gave a remarkably accurate IOP reading, similar to case 1.

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**STATISTICAL ANALYSIS**

For each case, we selected data segments reflecting a predominance of fluid flow because including other...
pressure data from the surgery would obscure the analysis of the pressure prediction model, which applies only to portions of the data wherein fluid flow is present. This selection was accomplished by visual inspection of each IOP graph with exclusion of points indicating static IOP or IOP spikes resulting from instruments pressing on the globe. One data segment showing a predominance of fluid flow was selected from each of the 10 cases and was analyzed using 2 separate methods of statistical analysis. First, we applied the well-known statistical tool of root-mean-square analysis, which is used to study accuracy of forecast (predicted) data with known (experimental) data.23 The second type of statistical treatment we performed was the $R^2$ analysis, which is used to determine the degree to which a model matches observed data.23

Case 1 (Figures 5 and 6) is an example of this approach for analysis. Although the graphs show pressure vs time data for a complete operation, only a fraction of this extensive data was chosen for analysis. Much of the IOP data during this surgery was excluded because there was no fluid flow. The 6.5-minute segment of fluid flow between 25 000 and 32 000 samples on the x-axis (18 samples per second) was used for the calculations, which appear in the first row of the Table. The static pressure differential of −0.664 is a correction for the position of the inline transducers of the IOP pack, which were attached slightly above the eye level of patient 1. (This calculation was made by comparing the IOP measured using the catheter transducer with the pressures taken with the inline transducers at atmospheric pressure, as described in the “Technical Considerations” subsection of the “Methods” section.) The other column headings in the Table refer to the root-mean-square error, the $R^2$ value, the absolute error, and the number of data points analyzed for each patient studied. In addition, peak IOP and high and low IOP during fluid flow are shown for each procedure.

The statistical data from all 10 patients in the Table have been compiled and appear in the legend of the Table. Inspection of these results verifies the precision of the indirect method of IOP measurement when compared with IOP data sampled directly from the midvitreous. In addition, the low static pressure differential indicates the surgeons were successful in placing the disposable transducers of the IOP pack close to the patient’s eye level.
The purpose of this study was to test a new system to determine dynamic changes in IOP during vitrectomy. The direct IOP data show for the first time, to our knowledge, that vitrectomy causes a chaotic pressure environment that is not detected by current console technology. These data are similar to measurements reported during cataract surgery. While the physiologic significance of these findings requires further study, it is likely that pressure variations documented in this article may be detrimental, particularly in susceptible persons with compromised ocular blood flow. When the intraoperative IOP fluctuations or baseline IOP are at their greatest, damage could result if the ocular blood flow and resultant perfusion pressure (mean arterial pressure – IOP) are simultaneously decreased. Rapid IOP changes across a 30-mm Hg range would be predicted to influence posterior segment blood vessels. The pressure alterations found in this study may underrepresent typical changes because the surgeons were carefully monitoring the changes, whereas in the absence of monitoring, pressure readings may be greater, particularly if fluid egress is impeded or external pressure is exerted during scleral depression or buckling.

In healthy volunteers, optic nerve head blood flow as measured by a laser Doppler flow meter and scanning laser system was significantly decreased when IOP was increased with a suction cup. Acute elevations of IOP led to decreases in juxtapapillary retinal and optic nerve head blood flow of 7.4% and 8.4% per 10-mm Hg IOP increase, respectively. In a second human blood flow study with healthy volunteers, a rapid and large decrease in mean ocular perfusion pressure of more than 100% resulted in a decrease of more than 80% in optic nerve head blood flow. In addition, the normal healthy eye is not able to autoregulate to maintain posterior ciliary artery blood flow velocities in response to acute large elevations in IOP. Patients with known cardiovascular disease or diabetes mellitus were excluded from this study, which was not designed to test functional outcomes.

Previous methods to record IOP during posterior segment surgery required insertion of a pars plana cannula. One report of using an inline pressure transducer to monitor IOP during surgery contained no data.

Figure 8. Intraocular pressure (IOP) time tracing of 21 minutes of vitrectomy for macular hole in case 2. The IOP ranges between 5 and 120 mm Hg. A indicates a stable IOP of 25 mm Hg during air-fluid exchange at the end of the case. This pressure corresponded exactly with the selected setting of 25 mm Hg on the vitrectomy console.
to verify its accuracy. Gas-forced infusion, the only commercially available technology for IOP measurement during surgery (Accurus surgical system; Alcon Laboratories), was shown in case 1 to result in actual IOP measurements that were at least 10 mm Hg higher than the set point on the machine. Furthermore, use of this technology usually was limited to the injection of gas into the vitreous near the end of the surgery. By contrast, the noninvasive and remarkably accurate IOP monitor that we report could provide an additional tool for vitreoretinal surgeons to evaluate and improve their procedures for all aspects of fluid flow during the entire operation. This approach could also lead to means to better control and dampen rapid fluctuations in IOP during surgery. Although the use of another disposable device in the operating room might increase costs, the potential to improve surgical outcomes would be justified.

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Figure 9. Comparison of calculated intraocular pressure (IOP) with measured IOP in case 2. The calculated IOP tracks the actual IOP during fluid flow only. Large spikes in IOP higher than bottle height (arrow) are due to pressure by forceps grasping the globe. During the air-fluid exchange at the end of the case, the calculated IOP remained at bottle height because there was no infusion fluid moving through the tubing.
Figure 10. Expanded view of comparison between calculated intraocular pressure (IOP) and measured IOP in case 2. There is a close correlation only during fluid flow; the IOP spikes higher than bottle height are the result of instrument manipulation of the globe.

Table. Data From All 10 Patients Undergoing Vitrectomy*

<table>
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<th>Patient</th>
<th>Start, ms</th>
<th>End, ms</th>
<th>SPD, mm Hg</th>
<th>RMS Error, mm Hg</th>
<th>$R^2$</th>
<th>ABS Error, mm Hg</th>
<th>No. of Samples</th>
<th>High IOP, mm Hg</th>
<th>Low IOP, mm Hg</th>
<th>Spike IOP, mm Hg</th>
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</table>

*Values in the columns “Start” and “End” denote the numbers on the x-axis of each patient’s data tracing, which were selected for analysis. These areas were picked by visual inspection of the IOP graphs and represented areas of fluid flow. Values in the column “SPD” represent the correction used for unequal alignment between the catheter transducer and the IOP pack during surgery. Values in the column “RMS Error” measure the accuracy of the prediction of the IOP during fluid flow by the pressure model. Values in the column “$R^2$” represent a second method of analysis to determine the fit of observed IOP data during fluid flow to the values produced by the pressure model. Values in the column “No. of Samples” refer to the exact number of electrical samples of pressure signals used in the analysis that correspond to fluid flow. Values in the columns “High IOP” and “Low IOP” show the highest and lowest pressures measured during the fluid flow portion of the procedure. Values in the column “Spike IOP” refer to rapid pressure spikes due to instruments, not tracked by the indirect IOP monitor, which is effective only during fluid flow. The mean values for all 10 cases are: SPD = 0.35 mm Hg; $R^2 = 0.9902$; RMS error = 0.0807 mm Hg; and ABS error = 0.0561 mm Hg.
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Clinical Trials Registration Required

As a member of the International Committee of Medical Journal Editors, Archives of Ophthalmology will require, as a condition of consideration for publication, registration of clinical trials in a public trials registry (such as http://ClinicalTrials.gov). Trials must be registered at or before the onset of patient enrollment. This policy applies to any clinical trial starting enrollment after March 1, 2006. For trials that began enrollment before this date, registration will be required by June 1, 2006. The trial registration number should be supplied at the time of submission.