

Validation of sensor for postoperative positioning with intraocular gas

Frank L Brodie¹
Kelly Y Woo²
Ashwin Balakrishna²
Hyuck Choo²
Robert H Grubbs²

¹Department of Ophthalmology, University of California San Francisco, San Francisco, ²Department of Medical Engineering, California Institute of Technology, Pasadena, CA, USA

Purpose: Surgical repair of retinal attachment or macular hole frequently requires intraocular gas. This necessitates specific postoperative positioning to improve outcomes and avoid complications. However, patients struggle with correct positioning. We have developed a novel sensor to detect the position of the gas bubble in the eye and provide feedback to patients in real time. In this paper, we determine the specificity and sensitivity of our sensor in vitro using a model eye.

Methods: We assessed the reliability of our sensor to detect when a gas bubble has deviated off a model retinal break in a model eye. Various bubble sizes representing the intraocular kinetics of sulfur hexafluoride gas and varying degrees of deviation from the correct position were tested using the sensor attached to a mannequin head with a model eye.

Results: We recorded 36 data points. The sensor acted appropriately in 33 (91.7%) of them. The sensor triggered the alarm every time the bubble deviated off the break (n=15, sensitivity=100%). However, it triggered the alarm (falsely) 3/21 times when the bubble was correctly positioned over the retinal break (specificity =86%).

Conclusion: Our device shows excellent sensitivity (100%) and specificity (86%) in detecting whether intraocular gas is tamponading a retinal break in a model eye.

Keywords: postoperative positioning, intraocular gas, vitrectomy, retinal detachment, macular hole, pneumatic retinopathy

Introduction

The use of intraocular gas for repair of retinal detachment and macular hole is a major component of vitreoretinal surgery and pneumatic retinopathy. Postoperatively, the patient is positioned so that the gas bubble is in apposition to the retinal break(s). This requires specific orientation of the head to ensure tamponade of all retinal breaks.

The importance and duration of postoperative positioning have been the subject of numerous studies and analyses.¹⁻⁸ While there is no consensus on duration needed and the ultimate impact of positioning on preventing re-detachment, a recent survey of retinal specialists showed that over 90% of them instruct their patients to position postoperatively.⁹ Positioning is important not only for achieving retinal reattachment but also for preventing postoperative complications such as cataract and glaucoma.¹⁰ In spite of the surgeon's instructions regarding the importance of proper head positioning after injection of intraocular gas, many patients are not compliant with the prescribed regimen. A study comparing the patients' perceived adherence to positioning and actual recorded head position highlighted this challenge.⁵ In this study, the authors found that the patients overestimated the time spent in correct positioning by twofold. In another study, researchers used gyro-accelerometers to continuously monitor head position.⁵ Although the correlation between the device readings and the actual bubble positions in the eye was never verified, the authors found that during the first 24 hours,

Correspondence: Frank L Brodie
Department of Ophthalmology,
University of California San Francisco,
10 Koret Way, San Francisco,
CA 94143, USA
Tel +1 415 710 2410
Fax +1 415 476 0336
Email frank.brodie@ucsf.edu

the average time spent in the correct head position was only 18%.¹¹ In addition, a large study of 145 patients with direct observation of the patients four times daily to assess positioning compliance showed that only one-third of the patients positioned correctly.¹² These studies tracked compliance either intermittently through observation or continuously through a large worn electronic sensor. To date, no study has developed a device with a clinical potential for either monitoring or providing feedback to patients. Additionally, no study to date has validated the sensor against actual bubble position relative to the retinal break, instead, relying on head angle as a surrogate.

To address both compliance and correct head positioning in patients with intraocular gas bubbles, we have engineered a small, simple, and low-cost electronic sensor and alarm to provide real-time monitoring of patients' head positioning. The sensor would be worn externally on the side of the patients' head. In this study, we test our external positioning sensor in three dimensions against a model eye with a modeled retinal break and gas bubbles of varying sizes to assess the fidelity of the sensor to intraocular gas position. Specifically, does the sensor correctly sound the alarm when the intraocular bubble is positioned off the retinal break (sensitivity)? Does it cause false alarms when the bubble is actually correctly positioned (specificity)?

Methods

The experiment was designed to assess sensor alarm fidelity to bubble position in a model eye. Our test conditions mimicked gas in the eye after pneumatic retinopexy, with pure sulfur hexafluoride (SF_6) gas first expanding then dissipating. We modeled the volume of an injected 100% SF_6 intraocular gas bubble on days 1, 3, and 5 postoperatively. One hundred percent SF_6 gas initially doubles in volume in the first 24 hours after injection and is then resorbed with a predictable half-life. Days 1, 3, and 5 of gas volume (assuming a 0.5 cm^3 initial injection) are 1, 0.57, and 0.32 cm^3 , respectively.¹³

This in vitro study did not use any biological specimens and as such was exempt from review by the Institutional Review Board.

Model eye

The radius of curvature of the posterior segment of the human eye is 12 mm. To replicate these conditions, a glass sphere with a radius of 12 mm was used. However, this yielded a greater volume (6.44 cm^3) than the human vitreous (4 cm^3). To compensate for this increase in volume, the gas volumes used in the model eye were proportionally increased from

the values described earlier. To replicate the conditions of a postoperative day 1 gas bubble, 1.61 cm^3 of air and 4.83 cm^3 of water were placed in the model eye. The day 3 model eye had 0.91 cm^3 and 5.53 cm^3 air and water, respectively. The day 5 model eye had 0.52 cm^3 and 5.92 cm^3 air and water, respectively. A 2 mm area on the globe was marked to identify the location of the retinal break.

Positioning sensor

The sensor consists of a 10 mm radius three-dimensional printed hollow sphere (Polylactic acid [PLA] transparent 2.85 mm diameter filament, Ultimaker, Geldermalsen, the Netherlands) containing 3.85 cm^3 of saturated sodium chloride solution and 0.34 cc air bubble. This bubble size was chosen so it would be proportional to SF_6 bubble size on day 5 in the eye (the smallest bubble used in this experiment). This was done to provide for maximum sensitivity of the sensor.

Two electrodes were placed at the opposite ends of the sphere. One of these electrodes was attached to a power source and the other to a simple circuit with an alarm light emitting diode (LED). When the gas bubble was not occluding one of the electrodes, the circuit would close (or connect) and the alarm would trigger (Figure 1A). However, when the air bubble covered an electrode, the circuit remained open (or disconnected) and the alarm did not trigger (Figure 1B), indicating the desired head position.

Experiment

A styrofoam head was used to hold the model eye in the orbit, and the positioning sensor was affixed to the ear of the styrofoam head. The retinal break was marked at 12 o'clock for head-up positioning and at the macula for face-down positioning. The sensor-electrode axis was aligned with the marked retinal break. Three types of deviation from the correct position were tested: 1) axial rotation, 2) anterior elevation (looking up) from a head-down position, and 3) lateral (head tilt) from a neutral position (Figures 2 and 3). Each deviation was tested at the angles of 20, 30, 45, and 58 degrees as determined by the digital angle gauge (Wixey Company, Sanibel, FL, USA).

In each position, two photos were taken to assess the intraocular gas position relative to the break in the model eye and to verify the corresponding status of the alarm light on the sensor. These were all repeated using the days 1, 3, and 5 intraocular gas bubbles in the model eye as described earlier.

Results

A total of 36 measurements were taken. Three variations of incorrect positioning were measured at progressive

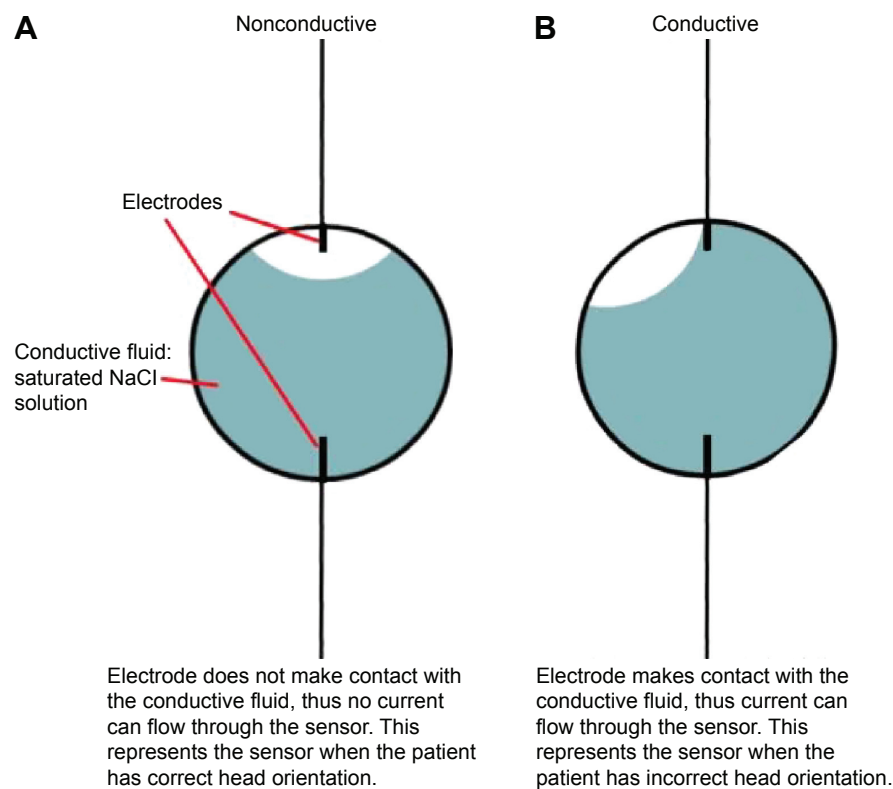


Figure 1 (A) Schematic of sensor in correct head position with the bubble occluding the electrode, thereby breaking the circuit. **(B)** Schematic of sensor with incorrect head position. The bubble is no longer occluding the electrode and the circuit is thereby complete, causing alarm to sound.

degrees of deviation from the correct position (Figures 2 and 3). Each position was tested using three different sizes of intraocular gas bubbles, which represented the kinetics of 100% SF₆ gas in the human eye. The position of the bubble relative to the retinal break and the alarm status were both recorded. These data and agreement between the sensor alarm and the intraocular gas bubble position are shown in Figure 4.

Both the sensor and the intraocular gas bubble behaved the same way across all three types of deviation from correct positioning (axial, tilt, and looking up).

Across all three gas bubble sizes (days 1, 3, and 5), the intraocular bubble remained on the model retinal break at 20 and 30 degrees of deviation, and the sensor, appropriately, did not sound the alarm. Similarly, across all three bubble sizes, the intraocular bubble was off the break at 58 degrees of deviation and the sensor, appropriately, sounded the alarm.

Discrepancy between the sensor and the bubble position in the model eye occurred with the day 1 (largest) intraocular bubble at 45 degrees of deviation: the sensor alarm triggered, but the intraocular bubble was still covering the break. This is not surprising given that the smallest bubble (commensurate with day 5 gas volume) was chosen for the sensor,

but on day 1 the intraocular bubble was significantly larger (1.61 cm³ of gas vs 0.52 cm³ of gas), so it was able to cover the break despite a large deviation from correct position. This difference between the small bubble in our sensor and the larger bubble in the model eye led to an overly sensitive sensor for day 1 measurements. However, as the intraocular bubble became smaller on days 3 and 5, it no longer covered the retinal break and the sensor continued to sound the alarm, now appropriately.

In summary, of the 36 recorded data points, the sensor acted appropriately in 33 (91.7%) of them. The sensor sounded the alarm every time the bubble was off the break (n=15, sensitivity =100%). However, it sounded the alarm (falsely) 3/21 times even when the bubble was correctly positioned over the retinal break (specificity =86%).

Discussion

In this experiment, we showed good fidelity between the sensor sounding the alarm for incorrect positioning when the intraocular bubble in the model eye did not tamponade the retinal break. Given the changing intraocular bubble size over time, a tradeoff between sensitivity and specificity was required in the design of the sensor. This is observed in the results, as the sensor had 100% sensitivity but only 86% specificity due to

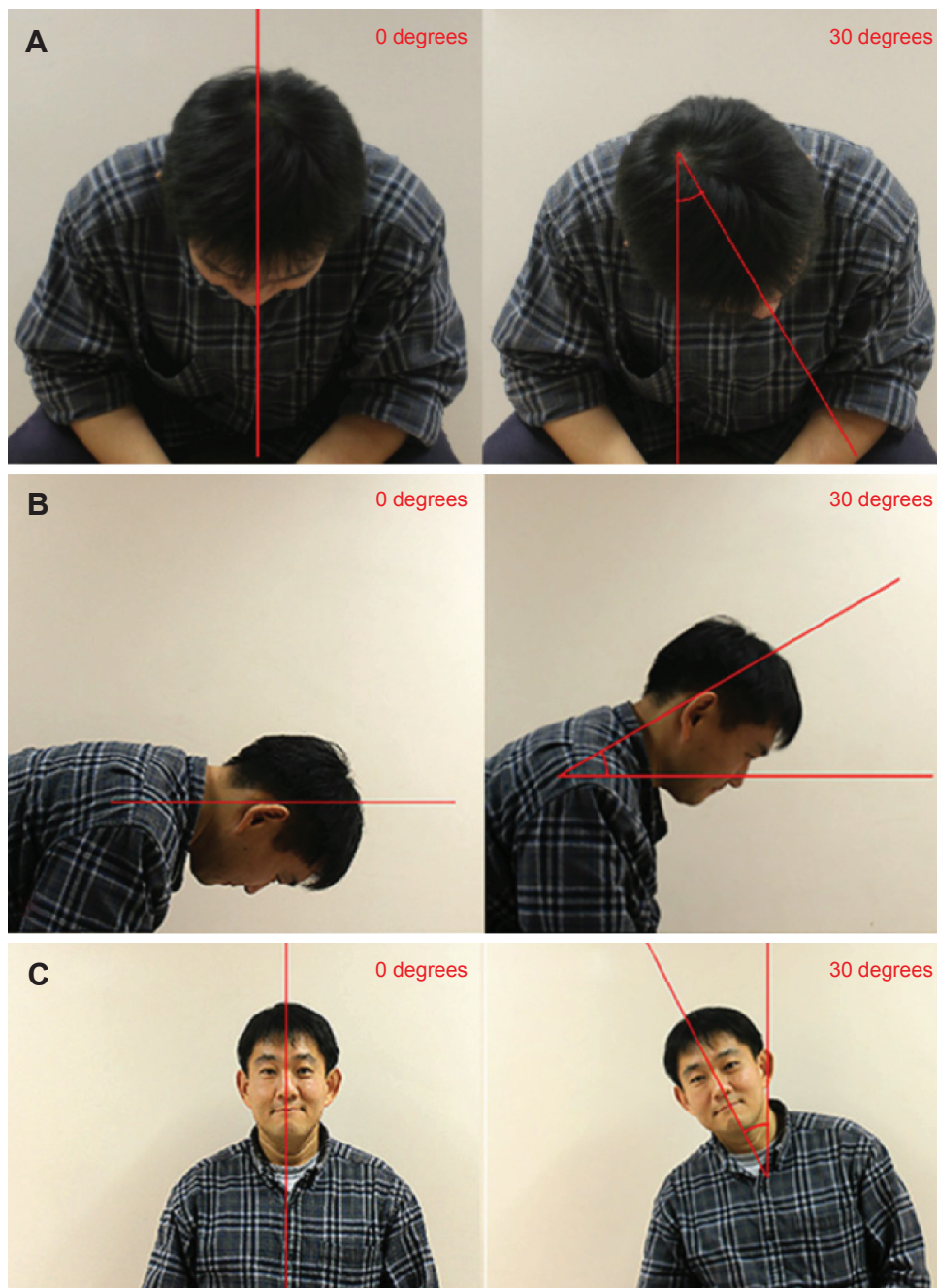


Figure 2 Positioning on human model.

Notes: (A) Axial rotation. (B) Anterior elevation (looking up) from a head-down position. (C) Lateral (head tilt) from a neutral position: 20, 45, and 58 degrees of deviation not pictured. Consent was obtained from the subject for use of the photography.

“false alarms”. These occurred when the intraocular bubble was at its maximum (and thereby able to cover the retinal break even at 45 degrees of deviation). However, as the bubble shrank on subsequent days, the break was no longer covered and the sensor sounded the alarm correctly.

Vitrectomy with an intraocular gas bubble is increasingly used to treat the vast majority of retinal detachments.^{14,15} Proper positioning after surgery is important not only in

surgical success but also for avoiding complications, including gas-induced cataract formation.¹⁶ A recent study shows that correct postoperative positioning dramatically reduces the incidence of postoperative cataract.¹⁷

However, proper positioning remains challenging for patients, with the majority overestimating the time spent in the correct position and ultimately not positioning correctly for much of the postoperative period.^{5,11,12} Previous studies

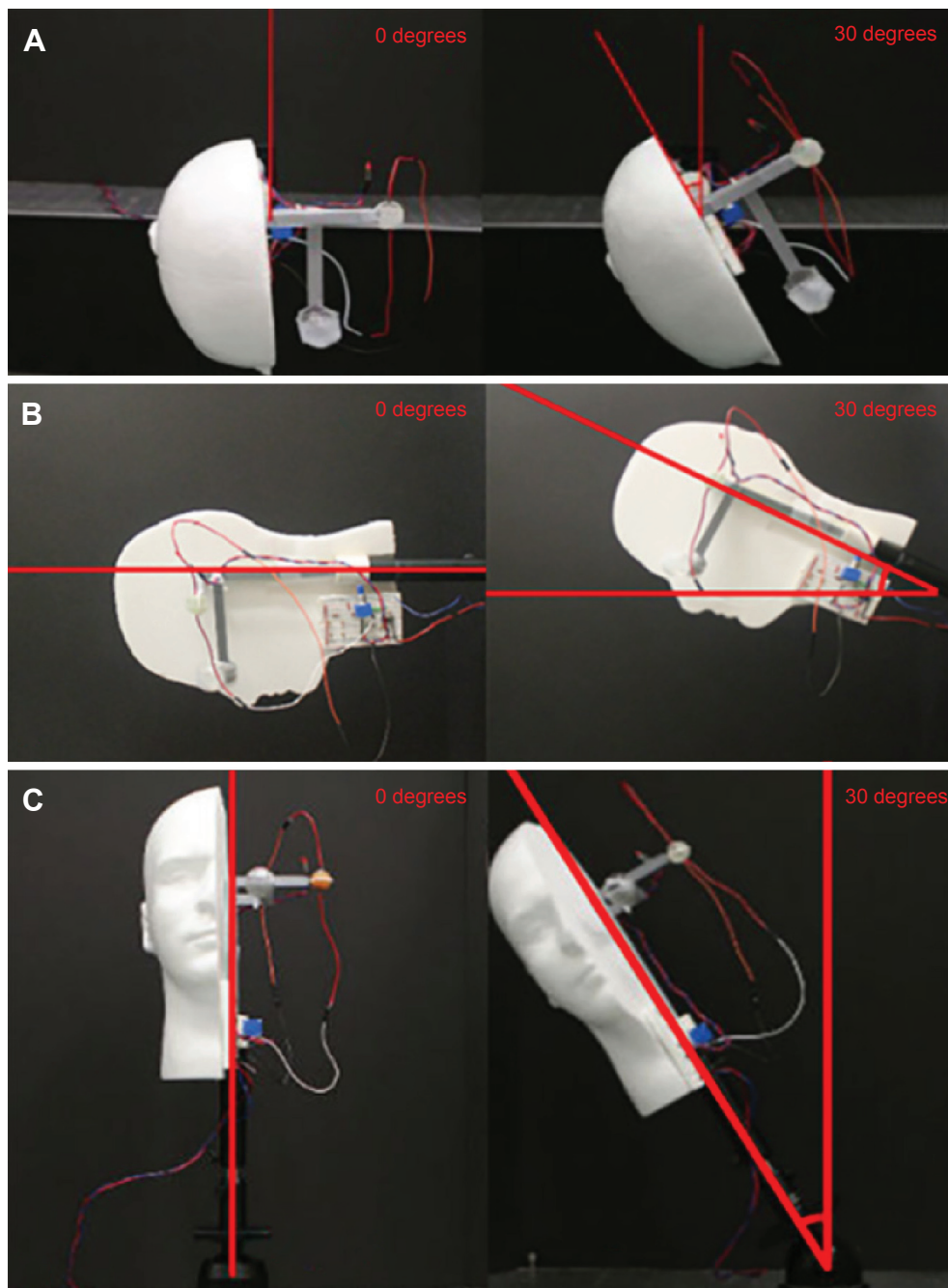


Figure 3 Positioning using styrofoam model head equipped with model eye and positioning sensor located at the ear to mimic how it would be worn by the patient. **Notes:** (A) Axial rotation. (B) Anterior elevation (looking up) from a head-down position. (C) Lateral (head tilt) from a neutral position: 20, 45, and 58 degrees of deviation not pictured.

have not validated their tracking devices against intraocular bubble position and have not accounted for the dynamics of changing bubble size.^{5,11} Our device will allow ongoing tracking of positioning and these data can further elucidate the relationship between quality and quantity of positioning and the risk of re-detachment. Additionally, our device is able to provide real-time feedback to patients to assist in correct positioning, and could even wake them from sleep (when most

of the incorrect positioning was observed).¹¹ Additionally, simple modifications to our device will allow recording of the amount of time the patients spent in the proper position.

Having shown that our sensor can accurately detect when the intraocular gas bubble is out of position in vitro, we plan to proceed with in vivo testing of sensor fidelity, and see if providing real-time feedback to patients affects positioning compliance and outcomes in the postoperative period.

	Degrees of deviation	Day 1 gas bubble				Day 3 gas bubble				Day 5 gas bubble			
		20	30	45	58	20	30	45	58	20	30	45	58
Face-down positioning (Macular hole) Deviation: looking up	Off hole in eye?	n	n	n	y	n	n	y	y	n	n	y	y
	Alert?	n	n	y	y	n	n	y	y	n	n	y	y
	Agreement	y	y	n	y	y	y	y	y	y	y	y	y
Face-down positioning (Macular hole) Deviation: lateral rotation	Degrees of deviation	20	30	45	58	20	30	45	58	20	30	45	58
	Off hole in eye?	n	n	n	y	n	n	y	y	n	n	y	y
	Alert?	n	n	y	y	n	n	y	y	n	n	y	y
Head-up positioning (12 o'clock retinal break) Deviation: head tilt	Degrees of deviation	20	30	45	58	20	30	45	58	20	30	45	58
	Off hole in eye?	n	n	n	y	n	n	y	y	n	n	y	y
	Alert?	n	n	y	y	n	n	y	y	n	n	y	y
	Agreement	y	y	n	y	y	y	y	y	y	y	y	y

Figure 4 Experimental data.

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Disclosure

A patent has been filed by California Institute of Technology on behalf of the authors; as such there is a potential for financial benefit if this concept is commercialized. The authors report no other conflicts of interest in this work.

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