Assessment of Postural Compliance After Pneumatic Retinopexy

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Introduction

Pneumatic retinopexy (PR) is an invasive surgical technique used to treat uncomplicated rhegmatogenous retinal detachment (not >1–2 retinal tears; detachments affecting the superior retina, and not >1–2 clock hours of extension).¹–³ The single-procedure success rate varies, depending on the source and ranges between 60% and 91%.²,⁴–⁹ The reasons for such variability remain not well understood. However, there are speculations pointing to several possible factors. Some of them are related to poor case selection by the retina specialist and some others to the lack of compliance with the postoperative instruction by the patients.³,⁰,¹⁰

The principle of the surgical techniques consists in injecting a bubble of gas tamponade into the vitreous cavity to block the passage of vitreous into the subretinal space through a retinal tear.¹–³,¹¹ To carry out this procedure, the patient must adopt a specific head positioning, which will vary according to the location of the retinal tear.¹² However, even in a neutral position, patients may have difficulty maintaining a fixed head position for prolonged period.

A significant and sustained displacement of the gas bubble (due to conscious or involuntary head movements) could lead to partial occlusion of the
retinal tear or even to a complete loss of contact between the tear and the gas tamponade; leading to the unavoidable failure of a PR. To date, no strategy or method exists to supervise/improve patient’s compliance with the postoperative instructions after a PR. Since the retina specialist relies solely on the fact that the patient accounts for his/her own behavior during the hours of procedure or even days after the operation, it is difficult to ascertain the possible cause of failure as well as other complications that may arise.

Real-time monitoring of patients’ vital biomarkers is a novel concept that uses the integration of electronic and digital hardware into the patient’s body. In the case of PR, the constant monitoring of the patient’s head position could potentially improve the single-procedure success rate. The main objective of this pilot study is to demonstrate the functioning and feasibility of a self-calibrating electronic device, that assesses the position of a patient’s head in real-time. The results will allow us to compare the real head position adopted by the patient, against the optimal position selected by the retinal specialist in three tridimensional axes.

Methods

The study was approved by the internal review board of the “Asociación para Evitar la Ceguera en Mexico, IAP” Hospital (“Association for Blindness Prevention in Mexico, IAP” hospital). The study was conducted according to the tenets of the convention of Tokyo (WNA 1975) and Good Clinical practices guidelines. All sensitive data were managed according to the Federal Law for Protection of Personal Data in Possession of Individuals (NOM-024-SSA3-2010), which is the local equivalent of the Health Insurance Portability and Accountability Act (HIPAA) rules of 1996. All participants signed an informed consent form before enrollment. Funds allocated for this research were provided by the authors.

We enrolled consecutive patients 18 years or older, with a clinical diagnosis of uncomplicated rhegmatogenous retinal detachment that fulfilled classic criteria for PR: Single retinal tear or multiple small tears clumped together or located within the same meridian, extension limited to the retinal periphery and equator and involving no more than 1 meridian, superior localization (between IX and III meridians) without visible vitreous tractions somewhere else and clear media. We excluded all patients with vitreous hemorrhage, proliferative vitreoretinopathy, glaucoma, uveitis, open/close globe trauma and patients with any cognitive deficiency, which may prevent them from fully understanding their pathology; a necessity for strict head positioning and physician instructions. We also excluded patients with any physical abnormality or deforming disease (advanced arthritis, and back and neck injuries) that prevented them from maintaining a fixed position for long periods.

Device Characteristics and Operation

For this study, we assembled a device composed of an ATmega32u4 microcontroller 8Hz (Adafruit Feather 32u4 Adalogger; Adafruit Industries, LLC, New York, NY), clocked at 8 MHz and at 3.3V logic; powered by a rechargeable 3.7V 1000 Ma, 3.3 × 5.2 × 0.3 mm lithium polymer battery, with an SPST on/off switch. For tridimensional orientation, we used a 9-DOF sensor accelerometer, gyroscope, and magnetometer (Adafruit 9-DOF Absolute Orientation IMU Fusion Breakout - BNO055; Adafruit Industries, LLC). Absolute orientation was measured by vectors (Euler angles in degrees) and vector deviation through axis orientation. Data were recorded in real-time and stored as an ASCII text-based file on a MicroSD card, through using a BNO055 breakout port (Fig. 1). The device was controlled with a couple of modified and concatenated open source programs (available in the public domain at https://github.com/adafruit/Adafruit_BNO055/tree/master/examples/sensorapi; https://gist.github.com/ladyada/13efab4022b7358033c7#file-adalogger-ino). Additional lines of codes were written to enable the specified measurement cycle and keep data recorded into a MicroSD card. The device was controlled with a couple of modified and concatenated open source programs (available in the public domain at https://github.com/adafruit/Adafruit_BNO055/tree/master/examples/sensorapi; https://gist.github.com/ladyada/13efab4022b7358033c7#file-adalogger-ino). Additional lines of codes were written to enable the specified measurement cycle and keep data recorded into a MicroSD card. The device was placed between two fabric compartments within an elastic headband (elastic polyester) that used a Velcro system (Velcro Companies, Boston, MA) to secure it in place. During the device design and setup, several tests were
done to assure 100% data acquisition and accuracy (data not shown).

The device’s main goal is the real-time assessment of the patient’s head angular placement, starting from a primary position selected by the physician on three tridimensional axes: X-axis (left and right neck rotation; “NO movement”), Y-axis (left and right lateral flexion of the neck; “MAYBE” movement), and Z-axis (flexion and extension of the neck; “YES” movement). The device was programmed to perform 1 single measurement every 200 ms, during the first 10 seconds of each minute, while the device is in use.

**Study Procedures and Statistical Analysis**

We documented general demographic data such as sex, age, and retinal detachment topography from each patient (number of retinal tears, localization, retinal detachment extension and macular on/off status). All patients underwent a regular PR with 0.4 mL undiluted (100%) intravitreal sulfur hexafluoride (SF6). The surgical procedure was done according to the most updated version of the original technique described by Hilton and Grizzard. Before the PR, all patients had a small individual training lecture about the importance of keeping an adequate head positioning after the procedure, including a rehearsal of the exact head position that he or she must keep thereafter depending on the retinal detachment characteristics.

Postoperatively, the device was powered by activating the on/off switch. The self-internal calibration algorithm started immediately within the next 60 seconds, the surgeon must move the band with the device from left to right to allow the electronic alignment of the axes. After self-calibration, the headband was firmly secured to the patient’s forehead. The headband must be tightened enough to prevent movement, but without causing pain or discomfort. Special care was taken in securing the device as close as possible to the study eye.

Once the headband was secured in place, the physician manually placed the patient’s head in the proper position and restricted all movement for the next 5 minutes. During this time, the device registered a primary position from where all deviation were recorded. Then, the patient was sent home with precise written instructions about proper head position. The proper topical antibiotic therapy was administered to the patient and he/she was advised not to take the headband off (Fig. 2). Written instruction included the following: A prescription for the eye drop drugs, (including common adverse effects), warning signs of endophthalmitis, the importance, and brief reasoning about why keeping the proper head position is essential for success of the surgical procedure, instructions regarding headband care during the next 24 hours (do not touch or tamper with the headband, do not power off, and do not take it off), emergency contact phone numbers, and the date of the next follow-up appointment.

The patient was asked to return the next morning for follow-up and intraocular pressure monitoring. The physician retrieved the headband and the information recorded on the MicroSD card. The data then were exported into an Excel spreadsheet (Excel 2010; Microsoft Corp., Redmond, WA) with an XLSTAT plug-in v18.06 (Addinsoft, New York, NY) for statistical analysis. General demographic data and retinal detachment characteristics were presented as means ± standard deviations. We defined a “partial deviation” of the patient’s head as any deviation of >15° but <30° from the primary position in any of the three axes, a “significant deviation” as a deviation of >30° from the primary position in any of the three axes, an “effective head position” only when the patient’s head had <15° of deviation from the primary position in all three axes at the same time, and “acceptable head position” as the sum of the time the patient kept his/her head with <30° of deviation from the primary position in all
three axes at the same time (the sum of effective position and partial deviation). The overall difference between the time the patient kept an effective position, partial deviation, and significant deviation among all three axes was assessed using a 2-tailed Mann-Whitney \( U \) test, with an \( \alpha \) value of 0.05 for statistical significance.

**Results**

We enrolled six consecutive patients (four male, three female; mean age at presentation, 61.6 ± 11.53 years; four right and two left eyes) who fulfilled all the inclusion/exclusion criteria. All patients had, macula-on retinal detachment. All retinal tears were located at the far periphery of the retina. Mean number of retinal tears was 1.33 ± 0.52. Mean number of affected clock hours was 2.5 ± 0.84. No patient reported any discomfort, overheating, trouble sleeping or pain due to the headband during use of the device (Table 1). Five of six enrolled patients had a complete retinal reattachment within the first 24 hours of follow-up (83.3%; 95% confidence interval [CI], 35.8–99.58). Two patients eventually required pars plana vitrectomy to achieve retinal reattachment (33.3%, 95% CI, 4.33–77.72) during the complete surgical follow-up of 1 month (not part of this study). These two patients included the one who never achieved retinal reattachment during the first 24 hours. One of these two patients required phacoemulsification due to cataract development.

During the follow-up interview, all patients stated that they followed positioning as instructed by physicians. None reported headache, neck pain, heating of the band, or significant discomfort during sleeping. None tampered, powered off, or removed the headband during the time between the PR and follow-up visit.

The device was worn for an average of 19.17 ± 2.1 hours (range, 15–21 hours). During this time, the device was able to make position measurements (every 200 ms, during the first 10 seconds of each minute) without power failures or program errors. Mean number of individual recordings was 57,670 ± 8663 measurements (range, 45,000–63,000).

After adding all individual measurements, where the patients kept an effective head position, mean time was 2.0 ± 1.67 hours (distributed along the whole measured period of time, Fig. 3). The Z-axis (flexion and extension of the neck; “YES” movement), where the patient’s head was kept with an effective positioning for 6.5 ± 5.5 hours (<15° deviation), had the least number of deviations. The hardest axis to maintain within the limits of an effective position was the Y-axis (left and right lateral flexion of the neck; “MAYBE” movement), with only an average of 2.5 ± 2.8 hours of effective positioning. The X-axis (left and right neck rotation; “NO movement”) was maintained with <15° of deviation from the primary position over a mean of 4.5 ± 3.3 hours in total.

The patients kept a “partial deviation” of the head (deviation of >15° but <30° from the primary position in all three axes at the same time) for a total of 1.33 ± 1.37 hours, distributed along the whole measured time period. The total time with an “acceptable” head position was 3.33 ± 1.8 hours (17.3% of the total time). The Z-axis had the least number of deviations, and was maintained within an acceptable range for a mean of 10.83 ± 4.59 hours. This was closely followed by the X-axis, which was maintained for 10.17 ± 3.69 hours. The hardest axis to maintain within an acceptable position again was the Y-axis with just 5.5 ± 2.54 hours.

In the remaining time, the device registered a significant deviation of the head (deviation of >30° from the primary position in any of the axes; Table 2).

There was a significant difference between the total

<table>
<thead>
<tr>
<th>No.</th>
<th>Age</th>
<th>No. of Tears</th>
<th>Size (DD)</th>
<th>Location (Meridian)</th>
<th>Effective Position</th>
</tr>
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<td>1</td>
<td>75</td>
<td>1</td>
<td>1.5</td>
<td>XII</td>
<td>RE, head straight in fowler</td>
</tr>
<tr>
<td>2</td>
<td>49</td>
<td>2</td>
<td>1</td>
<td>I-II</td>
<td>LE, right lateral flexion</td>
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<tr>
<td>3</td>
<td>48</td>
<td>1</td>
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<td>RE, right lateral flexion</td>
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<td>4</td>
<td>68</td>
<td>1</td>
<td>1</td>
<td>I-II</td>
<td>RE, right lateral flexion</td>
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<tr>
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<td>58</td>
<td>2</td>
<td>0.5</td>
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<td>RE, left lateral flexion</td>
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<tr>
<td>6</td>
<td>72</td>
<td>1</td>
<td>1</td>
<td>X-XI</td>
<td>LE, left lateral flexion</td>
</tr>
</tbody>
</table>

No, number; DD, disk diameter; RE, right eye; LE, left eye.

**Table 1. Clinical Characteristics Summary and Corresponding Position of the Head of Each Individual Patient**
time in which the patients held their heads within an acceptable position and the total time in which the patients had a significant deviation from the primary head position ($P < 0.001$). Regarding each individual axis, there was a significant difference in the number of hours with an acceptable position and the hours with a significant deviation on the Y-axis ($P < 0.003$). There was no difference between the X and Z axes.

### Discussion

Keeping a specific head position during the postoperative period is a fundamental part of many retinal surgical procedures, such as macular hole surgery, rhegmatogenous retinal detachment surgery, and subretinal hemorrhage displacements, among others. Therefore, instructing the patients to maintain a specific position is considered by many as a standard of care and an important aspect of the surgical procedure. Therefore, it is believed that the dedication and diligence with which patients follow the postoperative instructions could have a positive or negative influence in the overall surgical outcome.

The original technique of PR, as described by Hilton and Grizzard in 1986, is based on two main
principles: (1) The physical properties and surface tension exhibited by a bubble of gas tamponade, submerged in a semifluid media, such as the vitreous, and (2) the formation of a chorioretinal scar around the edges of a retinal tear after application of thermal energy (laser or cryotherapy), preventing the passage of liquefied vitreous into the subretinal space.

After the gas tamponade has been injected into the vitreous cavity, the surface tension generated between the two interfaces forces the gas into adopting a spherical shape (bubble). The strong cohesive forces generated between the gas molecules at the surface of the bubble, allow the complete occlusion of the retinal tear, without losing or deforming its shape, and without migrating into the subretinal space. The physical separation created by the gas tamponade between the liquefied vitreous and retinal tear restricts the passage of more vitreous into the subretinal space. Simultaneously, the Na\(^+\)/K\(^+\)-ATPase, located in the apical membrane of the retinal pigment epithelium (RPE), drives the existing subretinal fluid into the intravascular space, inducing reattachment of the retina. The buoyancy of the gas tamponade creates an ascending force vector that pushes the detached retina toward the RPE, favoring the chorioretinal adhesion even more. The greatest pushing force is exerted at the bubble’s apex. Therefore, one of the main goals after the injection of the tamponade is to position the apex of the bubble as close as possible to the geometric center of the retinal tear. However, these same physical properties prevent the gas bubble from being in perfect and smooth contact with the entire retinal surface and it will tend to move inside of the vitreous cavity in opposite direction to the head movements. A significant displacement of the bubble could lead to intermittent or permanent loss of contact between the gas tamponade and retinal tear, leading to surgical failure.

The mathematical model proposed by Eames et al. allowed us to predict a contact angle of an intravitreal gas bubble with retina tissue of approximately \(31^\circ\). Based on the assumption that the interface is asymmetrical around the vertical axis of the bubble, which is located ideally at the center of the retinal tear, any deviation of \(>15^\circ\) in any direction could potentially uncover an edge of the tear. We selected a cutoff value of 30% deviation in any axis as a measure of improper positioning, considering that this might induce a proportional 14° deviation of the contact angle of the gas bubble.

Despite the fact that all economic analyses have proven that PR is at least 50% more cost-effective than scleral buckle and pars plana vitrectomy for the treatment of retinal detachment, the 2016 preference and trends survey of the American Society of Retinal Specialist (ASRS, PAT survey 2016) showed that 36% of all non-United States retinal specialists surveyed accepted never to perform a PR. In addition, 45.7% perform less than one PR per month and only 12.7% perform one to three PR per month. The reason for such low popularity of the PR among non-United States retinal specialists is not well understood. However, we can speculate that the need for a close follow-up by the doctor, as well as the discomfort that strict head positioning poses for patients are a significant part of the problem.

The need for strict supervision of the patient’s position after retinal surgery has been recognized previously. The “Maculog” device, developed by

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**Table 2. Mean Number of Hours Where the Individual Axis Registered \(>30^\circ\) of Deviations From the Primary Position**

<table>
<thead>
<tr>
<th>No.</th>
<th>Average Time of Device Use</th>
<th>X-Axis</th>
<th>Y-Axis</th>
<th>Z-Axis</th>
<th>Total Deviation</th>
</tr>
</thead>
<tbody>
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<td>21</td>
<td>15</td>
<td>14</td>
<td>13</td>
<td>15</td>
</tr>
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<td>19</td>
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</tr>
<tr>
<td>6</td>
<td>15</td>
<td>0</td>
<td>7</td>
<td>15</td>
<td>14</td>
</tr>
</tbody>
</table>

Mean: 19.17 9.00 13.67 8.33 15.83

SD: 2.14 7.18 5.20 5.89 3.06

No, number; SD, standard deviation; Global deviation, percentage of the total registered time where the patients had their head with a significant deviation in all three axes at the same time.
Verma et al. \cite{11} is an ear-placed device aimed at registering the angular deviations in the position of the head, by means of a mercury-activated physical switch. In their study, the device was used in patients diagnosed with macular hole, after pars plana vitrectomy and strict face-down positioning. However, since the device relied heavily on a physical measurement with low gravitational sensitivity, the capabilities of the device to detect sudden, fast or sporadic changes in position was low. \cite{11} Another similar device designed by Leitritz et al. \cite{19} who built-in a sensor placed on a headband very similar to the one used in the present study. However, their device lacks the capability of self-calibration and their study was focused on patients with macular hole surgery as well. \cite{19} A significant improvement in devices design was introduced by Dimopoulos et al. \cite{20} who built-in the capability of having real-time acoustic and vibration feedbacks as reminders for the patients to help them to return into a proper position. The device was tested on patients after macular hole surgery with excellent results. \cite{20} Another innovation was introduced by Brodie et al. \cite{21} by adapting a bluetooth antenna to the device, which allowed control of the device by a mobile platform. However, to our knowledge, the prototype has been tested only on healthy volunteers. \cite{21}

The device used in the current report incorporates several significant improvements to the basic design, followed in most of the previous studies. First, a simplified design with modern microcomponents allowed us to integrate all circuits into a single microcontroller card. The result was a cheaper device with the significant decrease in size and, therefore, a more comfortable experience for the patient (total weight including headband, 151.4 g; device weight, 7.5 g; device cost, \$75 USD, including component and importation tax fees). Second, the incorporation of a rechargeable 3.7 V lithium polymer battery as a power source resulted in a decrease in the total weight, allowing to introduce a built-in power source into the headband as well. This feature might improve patients’ tolerability and its rechargeable property decreased the cost of operation. Finally, the most important improvements were the self-calibration property of the sensor and the real-time recording on a MicroSD card of the patient’s head position. The former allowed it to uniform the signals, which improved the response time of the device enabling it to record the smallest changes in vector orientation at a very fast rate (milliseconds). The latter allowed it to record a detailed log of the patient’s behavior during the postoperative time. Until now, all previous devices were limited to only sensing the change in position. Some of them could also emit an alert or register the number of times patients move outside a certain range. The speed and frequency of each individual measurement with the current devices enabled a detailed reconstruction of the events following the PR. For the first time, retinal specialists can assess patients’ adherence to postoperative instructions objectively during the unsupervised time elapsed between office visits. This kind of information could be used in the future to elaborate more detailed position nomograms and schedules to improve patients’ adherence and surgical outcomes. Furthermore, the basic design of the described system could be adapted easily to register other postural changes and broaden its use for other ophthalmologic procedures (macular hole surgery) and nonophthalmologic tasks (dyskinesia studies, head dystonia studies, chorea studies, sleep disturbances, and elderly care among others). We intentionally did not include vibratory or acoustic position reminders and designed the device as small and stealthy as possible for two main reasons. First, conversely to macular hole surgery where the face down position is the same for every patient, the final head position in patients after PR can be affected by several factors. Mainly, the location and size of the retinal tear, and the actual size achieved by the gas bubble. The latter could drastically affect what is considered an “effective” head position or the position where the retinal tear is completely covered for each individual patient, since it could drastically change the angle of contact of the bubble with the retina. Our study was designed based on a theoretical assumption that all injected gas bubbles achieved the same volume and that all patients had similar clinical characteristics. Therefore, it is impossible to accurately select a useful (real) cutoff value regarding the maximal amount of “tolerable” deviation from the primary position to emit an alarm. Second, part of the goals of this first stage was to observe patient behavior and instructions compliance as objectively as possible and without interference. A vibratory or acoustic reminder would have prevented us from achieving this objective. In the second phase of this research, we will include acoustic and mobile phone reminders through a built-in bluetooth antenna and a specially designed mobile phone application to improve patient’s compliance.

This study focused on patients with retinal detachment who were selected to undergo a PR. Since the vitreous remains in place, the injected gas
bubble tends to occupy a smaller volume in the vitreous cavity than after a pars plana vitrectomy. Moreover, there was no subretinal fluid drainage as a part of the surgical procedure. This means that small variations on the head angulation could be critical. Our results showed that the proposed head-positioning tracking device is able to work continuously without failure. The study also proved that even after a comprehensive explanation of the importance of maintaining a certain position, the adherence of the patients to postoperative instructions is minimal, since no patient was able to maintain an acceptable head position for more than 5 hours. The study also showed that maintaining a sustained lateral flexion of the neck poses the greatest challenge for patients (mean, 5.5 ± 2.54 hours). The probable reason is that muscles involved with the lateral flexion of the neck, like the rectus capitis anterior, rectus capitis lateralis, rectus capitis posterior major, the anterior muscles of the neck, longissimus, splenius, and scalenus anterior, are muscles of short action and usually untrained for sustained contraction. Therefore, they are prone to lactic acid accumulation and fatigue. As detailed in Table 1, most of our patients had retinal tears located at the X-XI and I-II meridians and only one had it exactly at the XII meridian. This means that most of them were instructed to keep a head position that included a certain degree of lateral flexion, matching our results.

In addition to the small sample and the fact that it is a pilot study, there are certain limitations that we would like to address. Although we were very careful in placing the device as close as possible to the study eye, the current design and capabilities do not account for more complex eye movements, such as incyclotorsion, excyclotorsion, pulsion, retropulsion, and gaze position, which could have an impact on the final position of the gas bubble in the intravitreous cavity. To correct this imprecision, the position sensor must be in close proximity with the ocular surface, like a contact lens or similar device. Another possible limitation is that perhaps measuring only 10 seconds of every minute was not representative enough of the events occurring during the entire minute. Since we registered hundreds of thousands of individual measurements from each patient (who shared a similar characteristic) we decided to use a nonprobability sampling technique, as a systematic sample. This could have induced a selection bias. Therefore, caution is strongly advised before making statistical inferences to the general population with this data. Finally, the speed of subretinal fluid absorption may vary among patients with different baseline characteristics (age, time since retinal detachment, complex or multiple retinal tears, and so forth). Therefore, the impact of a strict head positioning will be of paramount importance in some patients (especially if using short-acting gases), whereas it may not be that important in others.

In conclusion, our study shows that it is possible to have a real-time monitoring of vital biomarkers, such as patient head position, by means of a wearable device after a PR. Maintaining a sustained lateral flexion of the neck for more than 5 hours is difficult to achieve and physicians should be aware of this when planning future treatments. Larger and longer studies are needed to assess the real impact of not adhering to postoperative instructions regarding head position on surgical outcomes. The current design of our device, though functional, is still not optimal since it does not account for complex eye movements.
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