Behaviour of the Intraocular Pressure during Manual and Vented Gas Forced Infusion in a Simulated Pars Plana Vitrectomy

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Abstract

The purpose of the present is to measure and to compare the intraocular pressure (IOP) during manual and mechanical Perfluorodecalin (PFD) injection in 23 and 25-Gauge(G) simulated pars plana vitrectomy using a StellarisPC® vitrectomy system. A human eye model was developed and IOP recorded during infusion of PFD using three sensors, two located at the equator and one in an area corresponding to the macula (M) of the human eye. Three measurements were performed with 23 and 25G settings: during manual PFD injection by two vitreoretinal surgeons with different experience; during Venting Gas Forced Infusion (VGFI) of PFD at 8 psi and 12 mmHg of infusion; during VGFI of balanced salt solution at 30 mmHg of infusion in the closed eyeball model.

The manual infusion of both surgeons (in particular that of the surgeon in training) showed IOP values significantly higher (p<0.0001) and more scattered than the VGFI. The average IOP recorded during VGFI at 8 psi and 12 mmHg was higher than the set one, with both 23G and 25G (29.03 and 27.56 mmHg respectively). In the closed eyeball model, the actual IOP was steady but higher than the 30 mm Hg set. In all the experiments, except for two observations, the IOP recorded at the sensor M was significantly higher than that at the equator. In conclusion, potential damage due to excessive IOP fluctuations can be minimized using the mechanical infusion. Mechanical infusion prevents sustained pressure overshoot but it introduces a systematic pressure offset.

Keywords: Intraocular pressure, perfluorocarbons, vented gas forced infusion

INTRODUCTION

Pars plana vitrectomy (PPV) was first introduced in 1971[1,2] and since then it gained increasingly popularity as the preferred surgical procedure for the treatment of a large number of posterior segment disorders.[3-6]

The technologic development over the last years allowed the transition from the traditional 20-gauge(G) vitrectomy to the small gauges (23-, 25- and 27-G), transconjunctival and sutureless vitrectomy, with a significant reduction of complications and with an improvement in anatomic and functional outcomes. Nevertheless, in spite of the improved safety, PPV is still a challenging surgery where each stage can lead to intraoperative complications affecting postoperative visual recovery. Even in uncomplicated PPV, up to 14% of patients was reported to develop visual field defects[7-14.]

Although the relation between the surgical maneuvers and the visual field loss has not been totally elucidated yet, the most likely explanation is the reduction of the optic nerve perfusion pressure due to increased and fluctuating intraocular pressure (IOP)[15]. During PPV, several maneuvers can be responsible for IOP increase: scleral indentation, rise of BSS infusion to stop bleeding, injection of tamponades. In particular, IOP can sharply increase during the injection of Perfluorocarbon liquids to flatten the retina. Their injection can be performed either by the vented gas forced infusion (VGFI) system or manually by a syringe.

The purpose of the present study was to evaluate and compare the IOP values during manual injections and VGFI of Perfluorodecalin (PFD) in 23G and 25G simulated PPV using a commercially available vitrectome. IOP was measured with three custom made sensors in different areas of an eye model: two sensors were positioned at the equator and one in a zone corresponding to the macular region to evaluate if the IOP variations were similar within the eye.

MATERIALS AND METHODS

The present is an in vitro study and no patients or animals were involved. A polymeric eyeball model was designed in Solidworks 3D CAD (Dassault Systèmes SolidWorks Co., Waltham, MA, USA). The spheroidal hollow structure was fabricated according to an Additive Manufacturing approach

and specifically by 3D Ink-Jet Printing (Objet 30, Stratasys Ltd., Rehovot, Israel). The 3D prototype was built layer-by-layer, overlapping layers of 2 commercial polymers (a structural polymer and a sacrificial one used for the implementation of undercuts, easily removable subsequently by water jet) photo-crosslinked by ultraviolet (UV) irradiation, which are ejected through a special system of heads as a sort of ink-jet printer. The structural material of the model is the commercial UV-curable polymer VeroWhytePlusFullCure® 835, while the sacrificial one was the Support FullCure® 705, both of them commercialized by the same provider of the printer (Stratasys Ltd., Rehovot, Israel). The model is divided into two hemispheric shells. To avoid liquid leakage a circular ring on one of the two hemi-spheres was introduced to ensure a tightly closed system.

The eyeball model presents an inner diameter at the equator of 22.7mm and a central distance between the iris plane and the posterior pole of the sphere of 19.8 mm. The dimensions were chosen to simulate the average size of a human ocular bulb[16]. The shell thickness is 1.6 mm. The eyeball model presents three anterior circular openings (a,b,c), located at 3 mm from the iris plane and 120º apart from each other and three barbed connectors (1-3) .The three anterior circular openings allow the insertion of the cannulas. In order to fit 23 and 25-gauge diameters, two versions of the eyeball model were produced (Figure1).
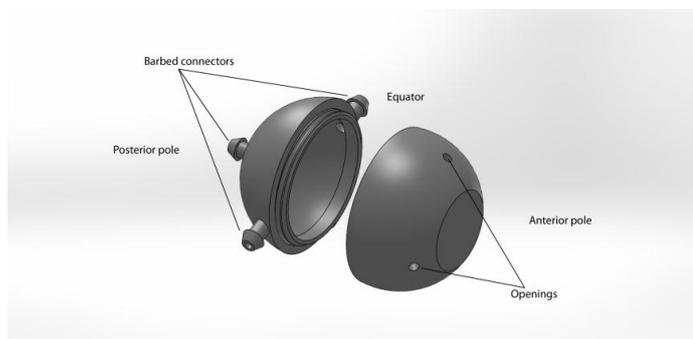

Figure 1: Illustration of the eye model.

The eye-model presents three anterior circular openings which fit 23 or 25 gauge infusion cannulas and three barbed connectors linked to three pressure sensors by three silicon tubes.

The three barbed connectors were built together with the eyeball model during the prototyping fabrication step to fit three pressure sensors (HMAM250UZ7H5, First Sensor AG, Berlin, Germany) connected to the bulb with silicone tubes with an inner diameter of 2 mm. One of the three connectors (M) was positioned in the area corresponding to the macular region and opposite to the infusion port (a). The other two were positioned on the antipodal points at intersection of the geometric equator plane with the meridian plane.

The experimental setup was composed by three main sub-systems: the first was labelled as the physical interface, namely the eyeball connected with the three pressure sensors; the second was represented by an Analogic to Digital Converter (ADC) and an electronic circuit specifically designed for the application requirements; the third was a custom Graphical User Interface (GUI) created in NI LabVIEW® (National Instruments Corporation, Austin TX, USA) for the analysis and post processing of acquired pressure values (Figure 2).
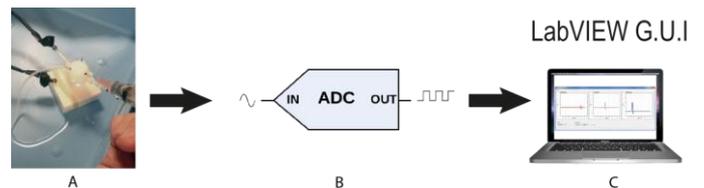
Figure 2: Schematic drawing of the experimental setting:

A) The physical interface - the eyeball connected with the three pressure sensors; B) the Analogic to Digital Converter (ADC); C) the LabVIEW® Graphical User Interface (GUI) which analyzes and post processes the acquired pressures.

The measure range of HMAM250UZ7H5 pressure sensors is 0-250 mbar. Each sensor was calibrated by means of a standpipe piezometer to ascertain the absence of systematic errors as offset or scale factor between the transducers. The accuracy of the three sensors was above 99,5% over the entire working range.

The ADC with a 12-bit resolution and a 10 Hz sample frequency converted the Full Scale Span output of 4 V. The electronic board hosting the ADC was connected via a USB cable to a laptop, where the LabVIEW® GUI displayed in three different charts the synchronized trends of the acquired pressure data versus the elapsed acquisition time.

The IOP in the eye model was measured in four sets of experiments performed by means of a commercially available vitrectomy machine (StellarisPC®, Bausch+Lomb,New York, USA).

In the first experiment to simulate a real vitrectomy the (a) port was connected to the infusion set at 12 mm Hg, in the (b) port a light fiber was inserted and through the port (c) PFD (F-Decalin, Fluoron Gmbh, Ulm, Germany) was injected manually by two different vitreoretinal surgeons, named Doc 1 and Doc 2, one experienced and one in training respectively. Both surgeons repeated the PFD manual injection twice. The time elapsed from the start was recorded.

In the second experiment, the settings were the same but the port (c) was connected to the VFGI system of the machine in order to inject the PFD at 8 psi. In the third experiment, the ports (b) and (a) were closed by plugs and in port (c) was simply injected by VGFI BSS at 30 mm Hg simulating the static

condition which may occur during a real vitrectomy. The eye models were located on an operating table at the usual height of the patient's head in a real vitrectomy.

Each experiment was repeated with both the 23-gauge and the 25-gauge eye models.

RESULTS

The mean duration of PFD manual infusions was 25 sec for the more experienced surgeon (Doc 1) and 18.5 sec for the colleague in training (Doc 2) using the 25-gauge set, and 41 and 36.5 sec respectively with the 23-gauge set. In the simulated 23-gauge PPV the mean IOP was 37.01 ± 8.48 mm Hg (min 8.46, max 65.5 mm Hg) during manual infusions of Doc 1, and 72.89 ± 23.14 mm Hg (min 23.39, max 120.7 mm Hg) during PFD injections of Doc 2.

With the 25G setting the mean IOP was 39.24 ± 14.09 mm Hg (min 11.24, max 67.14 mm Hg) and 64.75 ± 18.79 mm Hg (min 21.38, max 93.38 mm Hg) for Doc1 and Doc2 respectively.

Doc 2 induced significantly higher IOPs than Doc 1 with both the 23 and 25 G ($p<0.0001$).

Mechanical infusion was measured during 35 sec: the mean IOP was 29.03 ± 0.86 mm Hg (min 26.16, max 30.82 mm Hg) and 28.31 ± 0.4 mm Hg (min 25.28, max 28.99 mm Hg) using the 23 and 25 G respectively.

Comparing the IOP measurements of mechanical and manual infusions, we observed a significant difference between the VGFI versus both surgeons, both in 23 and 25 G: IOP during VGFI was significantly lower ($p < 0.0001$).

When comparing 23 and 25 G settings the IOP was significantly higher with the 23 G than with the 25 G in both the mechanical and Doc 2 infusions ($p < 0.0001$).

Figure 3 illustrates the IOP trend during the whole length of VGFI and manual infusions with 23 and 25 G sets. As shown IOP during VGFI was steadier than that recorded during manual infusions of both surgeons; IOP during Doc 1infusions was steadier than in Doc 2 injections.
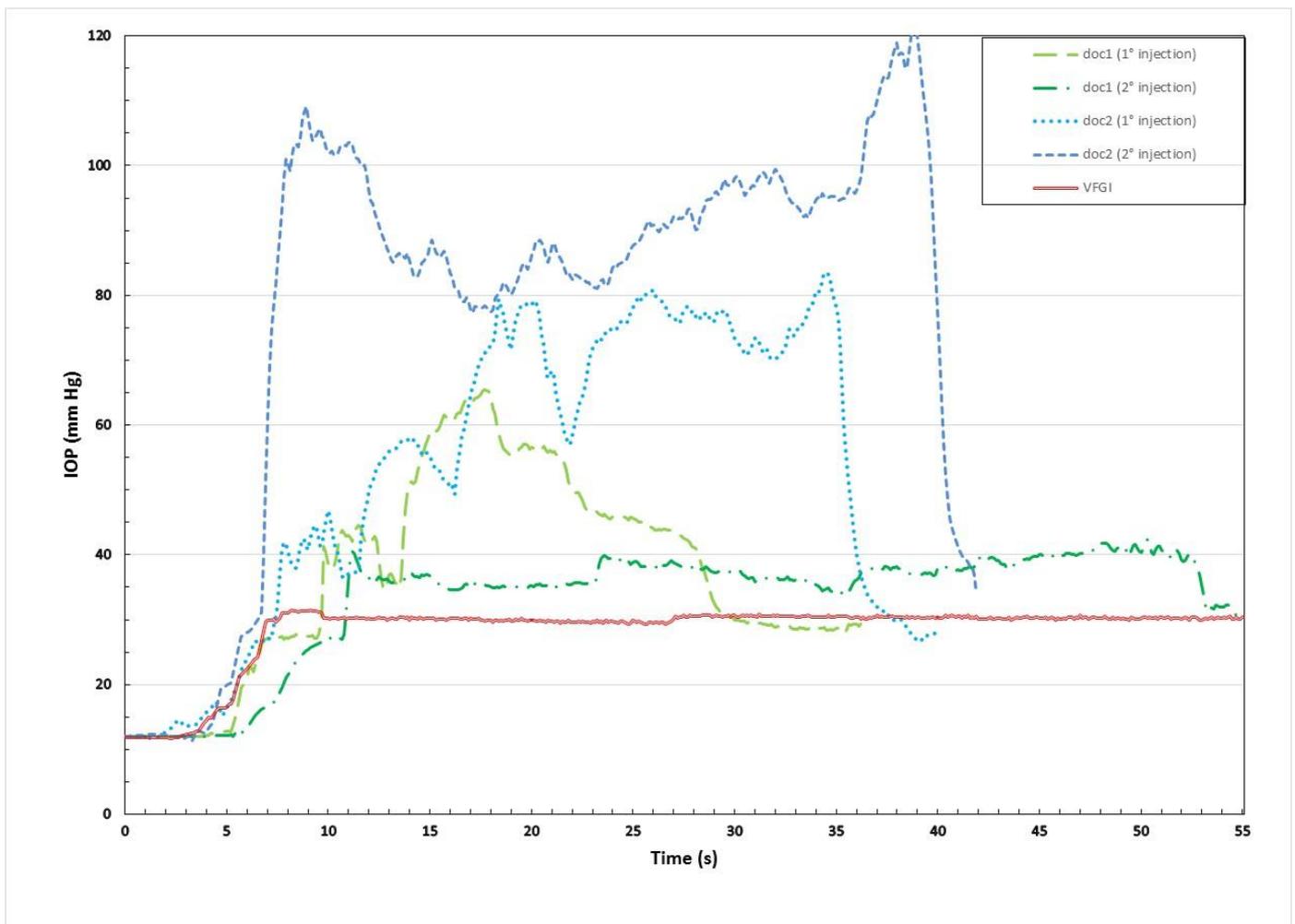
Figure 3. Time-dependent analysis of the IOP trend during the VGFI and the manual infusions of Perfluorodecalin with 23G setting.

Since one of the main purposes of the present study was to investigate how the infusion maneuvers affect the IOP in peculiar sites of the eye bulb, we performed a comparison between the IOP values recorded by the macular (sensor M) and the equatorial probes (sensors 1 and 3).

As shown in Table 1 and 2, the IOP recorded by the macular sensor was in almost all the experiments significantly higher (p < 0.0001) than the ones measured equatorially.

Table 1: 23-gauge set. Actual Intraocular pressure (IOP) measured by the three pressure sensors during manual injections and Vented Gas Forced Infusion (VGFI) of Perfluorodecalin and comparison of IOP values detected by the three probes.

IOP Values	VGFI at 8 PSI (mmHg)			Manual by Doc 1 (mmHg)			Manual by Doc 2 (mmHg)		
	Min	Max	Mean±SD	Min	Max	Mean±SD	Min	Max	Mean±SD
Sensor 1	26.16	28.80	28.07±0.33	16.78	63.86	36.06±8.45	23.39	117.36	71.04±22.79
Sensor M	28.24	30.82	30.04±0.32	18.92	65.50	38.51±8.35	25.97	120.70	74.44±23.07
Sensor 3	27.29	29.43	28.97±0.27	17.22	63.80	36.50±8.39	23.90	120.45	73.18±23.47
Mann-Whitney test	U (p-value)			U (p-value)			U (p-value)		
Sensor 1 vs M	300.000 (p<0.0001)			234059.500 (p<0.0001)			218102.000 (p=0.001)		
Sensor 1 vs 3	16117.500 (p<0.0001)			294890.000 (p=0.058)			227313.000 (p=0.024)		
Sensor M vs 3	831826.000 (p<0.0001)			375668.000 (p<0.0001)			253910.500 (p=0.203)		

Mann-Whitney U test was performed to evaluate statistical significance.

Table 2: 25-gauge set. Actual Intraocular pressure (IOP) measured by the three pressure sensors during manual injections and Vented Gas Forced Infusion (VGFI) of Perfluorodecalin and comparison of IOP values detected by the three probes.

IOP Values	VGFI at 8 PSI (mm Hg)			Manual by Doc 1 (mm Hg)			Manual by Doc 2 (mm Hg)		
	Min	Max	Mean±SD	Min	Max	Mean±SD	Min	Max	Mean±SD
Sensor 1	25.28	28.24	27.83±0.21	11.24	65.50	41.71±14.51	21.38	91.62	63.56±18.76
Sensor M	26.67	28.87	28.51±0.19	13.45	67.14	43.83±14.12	23.83	93.37	66.13±18.76
Sensor 3	26.35	28.99	28.69±0.20	12.12	66.06	42.56±14.32	22.07	93.00	64.57±18.8
Mann-Whitney test	U (p-value)			U (p-value)			U (p-value)		
Sensor 1 vs M	5552.500 (p<0.0001)			95478.000 (p<0.0001)			56982.000 (p=0.007)		
Sensor 1 vs 3	5347.500 (p<0.0001)			103976.000 (p=0.096)			60918.500 (p=0.205)		
Sensor M vs 3	146146.500 ((p<0.0001)			120391.000 (p=0.023)			69153.000 (p=0.090)		

Mann-Whitney U test was performed to evaluate statistical significance.

Table 3: IOP recorded by the three sensors during Vented Gas Forced Infusion of BSS at 30mm Hg in closed eyeball with 23 and 25 gauge settings.

	25-gauge (mm Hg)			23-gauge (mm Hg)		
IOP Values	Min	Max	Mean±SD	Min	Max	Mean±SD
Sensor 1	46.62	47.75	47.29±0.17	36.79	43.66	42.89±0.57
Sensor M	48.06	48.95	48.39±0.11	38.12	45.73	44.63±0.67
Sensor 3	47.62	48.38	47.98±011	36.92	44.41	43.59±0.70
Mann-Whitney test	U (p-value)					
Sensor 1 vs M	0.000 (p<0.0001)			9510.500 (p<0.0001)		
Sensor 1 vs 3	510.000 (p<0.0001)			75163.500 (p<0.0001)		
Sensor M vs 3	5565164.000 (p<0.0001)			515915.500 (p<0.0001)		

Mann-Whitney U test was used to compare IOP values detected by the three probes.

During the VGFI of BSS at 30 mm Hg in closed eyeball the IOP measured was 43.70 ± 0.65 and 47.89 ± 0.13 mm Hg in 23 and 25G respectively. Similar to the first and the second experiments the IOP at sensor M was significantly higher ($p < 0.0001$) – Table 3.

DISCUSSION

During vitrectomy, IOP fluctuations may represent a main issue; it was shown that IOP during vitrectomy can range from 0 to 120 mm Hg[17,18]. These IOP fluctuations can increase the risk of intraoperative and postoperative complications and may compromise recovery of visual function after surgery,[19-22] especially if the optic nerve perfusion pressure is lower than normal.

Clinical and animals studies investigated the effects of high infusion pressure during PPV on retinal morphology and function[23, 24, 25].

To fine-tune the infusion pressure during vitrectomy, besides the traditional gravity system, the vented gas forced infusion system was developed for rapid infusion pressure adjustments. With this system, the infusion pressure is generated by the device and results from the amount of pressurized air in the bottle containing the infusion fluid: the higher the pressurized air the greater the amount of infusion fluid driven forward.

PFCL fluids are ideal intraoperative tools in vitreoretinal sugery[26]. They are widely used, especially in Europe, to flatten the detached retina during vitrectomy.

Perfluorodecalin is a frequently used PFCL; its infusion may be performed either manually by the surgeon or mechanically by the VGFI system. The first option is usually chosen in clinical practice although the IOP during the maneuver can be just grossly estimated by indirect signs like the pulsation of the optic nerve vessels, the changes in the wall reflex at the macular region, the optic disk whitening.

In our experiments we found a much higher IOP with manual infusion.

Moreover, with VGFI the IOP values were steady whereas in manual infusions we observed significant IOP fluctuations. Compared with the more experienced surgeon, the surgeon in training induced higher IOP and greater and more frequent IOP fluctuations during this maneuver, irrespective to the size of the infusion.

Since a steadier IOP value is supposed to induce less fluid turbulence, the VGFI seems a safer way to prevent the fragmentation of the PFD stream and the displacement of resulting small bubbles in the subretinal space through the retinal breaks.

During the VGFI the IOP proved higher than the set one. This finding supports the results reported by previous Authors. Moorhead et al showed that during gas-forced infusion the real IOP was about 10 mm Hg higher than intended[17]. Okamoto et al developed an equation to convert the VGFI setting to the actual IOP as they observed that the real IOP tended to be slightly higher than the one set during mechanical infusion[27].

This finding may suggest to use lower pressure settings in patients with ischemic vascular diseases or optic neuropathies.

We aimed to ascertain if different gauge systems affect in different way the IOP trends. Our results were discordant; on the one hand similarly to some previously published data in the majority of our experiments the infusions by 23 G cannulas resulted in higher IOP[28,29] on the other hand according to other Authors we found higher IOP during Doc 2 infusions with 25G setting [30].

We investigated whether the pressure was differentially transmitted to various areas within the bulb. The IOP readings at sensor M, corresponding to the posterior pole, were significantly higher than those measured by sensor 1 and 3, located at the equatorial level.

This result was consistently detected throughout the investigations, except for two observations relative to Doc 2 manual infusions.

We suggest that a focal pressure rise may occur due to the position of sensor M opposite to the infusion cannula. A focal chorioretinal damage on a "vulnerable point" contra lateral to the infusion port was firstly postulated by Hirata et al and Hasumura et al.[31,32].

It was suggested that this focal pressure increase was the principal mechanism of damage caused by air infusion in fluid-air exchange or by BSS infusion[33].

It's worth noting that the IOP increase in a vitrectomy can be further affected by several other factors (i.e extraction of the instruments with the exhaust cannula held open) as previously described by Kim et al.[34].

Our results should be considered with some caution because they were obtained using a rigid not expandable eye model made of polymer. The stiffness of the synthetic polymer could mismatch the rigidity of the scleral collagen and the real IOP in human eyes during PFD infusion may be slightly lower than the one measured in our study. In addition, during manual infusions of PFD in the eye model the surgeons could not check the indirect signs of IOP rise (optic disk pallor, pulsation of the arteries at the optic nerve head, generalized constriction of the retinal vessels) which in clinical practice are a guide while performing this procedure.

Despite several limitations, the methods used in the present study were applied in a planned rigid manner thanks to the use of an in vitro model with the attempt to control the largest possible number of variables. To the best of our knowledge, this is the first study that evaluates and compares IOP during VGFI and manual infusion of PFD.

This study allows a better understanding of vitrectomy fluidics during PFD infusion extending previously published data and provides evidence of a steadier intraocular pressure using the mechanical rather than the manual injection of PFD.

Disclosure/conflict of interest

Marco Dal Vecchio: none; Antonio Maria Fea: none; Roberta Spinetta: none; Simone Luigi Marasso: none; Matteo Cocuzza: none; Luciano Scaltrito: none; Giancarlo Canavese: none.

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