An Ocular Compression Device for Reduction of Elevated Post Anesthetic Intraocular Pressure

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***Abstract*—Rise in Intra Ocular Pressure (IOP), after administration of regional ophthalmic anesthesia for surgery, is a commonly observed clinical phenomenon. Rise in IOP increases risk of retinal ischemia and leads to surgical complications. The current clinical practice for reduction of IOP, after delivery of local anesthesia, is manually administered digital compression. The highly subjective nature of manual compression, results in unknown duration and magnitude of the pressure applied, thus limiting the clinical effectiveness of the procedure. The work presented here addresses the need for a device that delivers all the benefits of digital compression, while eliminating the uncertainty and risks involved. Design, development and clinical validation of an air pressure based compression device have been presented in this paper. This device makes the compression procedure safe and reliable by quantifying all compression parameters applied and considering safety limits for individual subjects.**

I. Introduction

Peribulbar anesthesia/block is a commonly used regional anesthetic technique for performing ophthalmic surgery. In this technique the local anesthetic agent is injected outside the muscle cone in the gap between the eyeball and the orbital wall which is filled with fat tissue. While achieving the desired objectives, of akinesia, analgesia and temporary loss of vision, administration of anesthesia also results in an increase in the fluid volume inside the eye socket. This increase in fluid volume results in an increase in the external pressure acting on the walls of the globe, which in turn increases Intra Ocular Pressure (IOP) [1].

Elevated IOP for long durations can occlude blood flow and cause permanent damage to the eye. Intermittent ocular compression accelerates perfusion of the anesthetic agent by increasing the pressure gradient thereby increasing fluid absorption by the surrounding tissue [2]. Periods of decompression allow vascular pulsations to occur preventing occlusion of blood flow. Digital compression is the standard clinical procedure followed for the reduction of IOP prior to the surgery [3]. The procedure involves the anesthetist using his/her fingers for application of pressure on the globe. Periods of decompression are provided in between to allow vascular pulsations. This process is continued till the required level of softness of the globe is achieved.

The risks involved in digital compression revolve around the fact that the procedure is subjective and that the pressure applied by the anesthetist on the patient's eye is unknown. If the pressure applied on the globe is too high it can occlude the central retinal artery and if it is too low the globe may not soften adequately. The frequency of intermittent compression used should be optimum to allow vascular pulsations [4]. The total duration of digital compression should be maintained such that it does not cause optic nerve damage [5]. Hence it is necessary to quantify the parameters involved in digital compression.

None of the existing solutions address all these problems. I-wait oculopressor, which is a gravity assisted ocular compressor lacks provision to apply intermittent compression or vary the magnitude of pressure applied [6]. Honan's balloon which is an air pressure based ocular compressor is a manually operated device thus bringing in operator error [7]. Both these devices lack adequate safety features. There is an unmet clinical need to develop a customizable device which can provide intermittent ocular compression within a measurable and safe pressure range in a precise and repeatable manner for precise time duration.

In this work we present the design, development and validation of an automated air compression based Ocular Compression Device (OCD) that enables effective and quantifiable pressure application, for reduction of IOP. Once the parameters are set, the device automatically performs intermittent compression and decompression of the eyeball, allowing vascular pulsations. Clinical trial results using a prototype device have also been discussed which shows that the device helps in significantly reducing elevated IOP.

II. Ocular Compression Device Design

As discussed above, the purpose of the device is to apply a precise amount of pressure on the eye for a specified amount of time with provisions to change the magnitude of pressure applied, compression and decompression cycle periods and the total duration of application. The functional

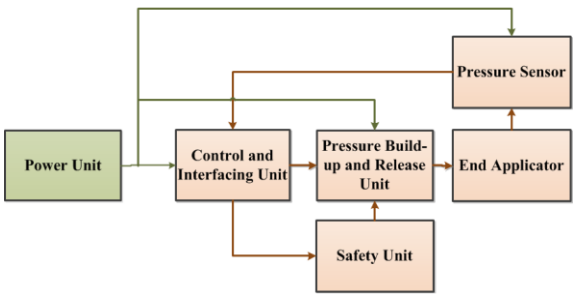

Figure 1. Functional Block Diagram

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block diagram of the device designed is shown in Fig. 1.

The control and interface unit ensures that the correct amount of pressure is being applied on the eye by the end applicator for the specified duration of time, with adequate compression and decompression periods. It takes user input and controls the pressure build-up and release unit which in turn builds pressure in the end applicator during compression and releases pressure during decompression. The end applicator has to be conformal with the contour of the eye ball, to ensure uniform pressure application. The pressure sensor measures the pressure that is applied on the eye at any given instant and gives continuous feedback to the control unit. The safety unit prevents excessive pressure build-up which can otherwise cause serious damage to the eye. This unit has to prevent damage to the eye in the case of electronic system failure.

III. Development And Experimental Validation

A prototype OCD was developed that delivers automated ocular compression in a precise and safe manner. After considering various options for pressure build-up, an air pressure based ocular compression system was finalized taking into account the need to apply variable pressure. Ease of availability of air pressure sensors in the pressure ranges applicable also supported the decision. The implementation block diagram of the device is given in Fig. 2. It shows how each component in the device is electrically or mechanically connected to each other.

A DC motor mechanically coupled to an air pump builds the required pressure. A normally open solenoid valve releases the pressure during decompression and excessive pressure build-up. A bellow made of silicone rubber, which expands when air pressure is built inside it acts as the end applicator. Air is pumped into the bellow connected to the pump through silicone tubes and the pressure built inside is transferred on to the eye by placing it in position with the help of a head band assembly.

A MEMS air pressure sensor MPXV4006GC7U with an operating range of 0 mmHg - 50 mmHg and accuracy of ±0.5 mmHg senses the pressure inside the bellow. The range was selected considering the fact that pressure applied on the eye never exceeds 40 mmHg [5].

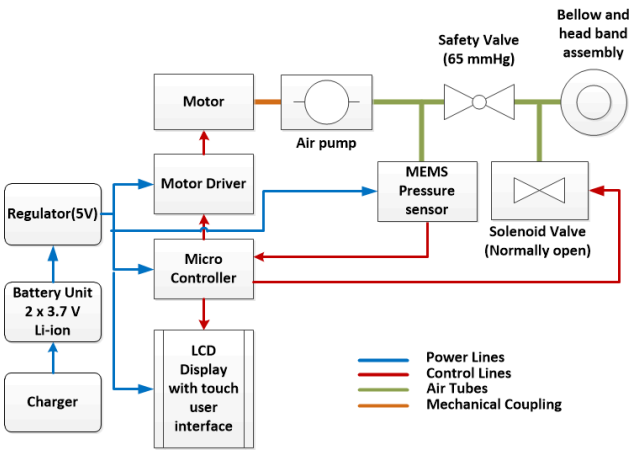

Figure 2. Implementation block diagram of OCD, giving the details of how each component is electrically or mechanically connected

All control operations are carried out by a microcontroller (Atmel328). The microcontroller samples the MEMS pressure sensor at 1 kSa/s and implements a PID controller which controls the pressure applied on the eye by giving a PWM (Pulse Width Modulated) output to a motor driver. The motor driver (L293D) delivers the power required to run the motor, the speed of which is controlled by the PWM duty cycle. It also controls the solenoid valve. A touch screen LCD display is used to provide user interface with the device.

Patient safety is ensured by using the normally open solenoid valve which automatically releases the pressure in case of power failure. The valve also makes sure that there is no accidental pressure build-up in the bellow when the device is not in operation. An alarm mechanism is also incorporated to warn the doctor in case of excessive pressure shoot up inside the bellow. The alarm also notifies the doctor upon completion of compression procedure. In addition to the above features, a mechanical safety valve is also used which ensures safety by limiting the maximum pressure that can be applied to 65 mmHg, in case of electronic system failure.

The power supply section of the device includes a rechargeable battery unit, a voltage regulation system and a charging unit for the battery. The device carries two Li-ion batteries of nominal voltage 3.7 V and a capacity of 2000 mAh. Fig. 3 shows the device packaged in a compact ABS enclosure in operation on a human subject.

An experiment was carried out to verify that the pressure built inside the bellow which is placed on top of the eye is transferred to it. This was done by strapping the bellow and head band assembly around a precision weighing scale and calculating the pressure transferred to it when a known pressure is built inside the bellow. The effective area of contact of the bellow was found out and was used to calculate the pressure applied along with the weighing scale reading. The pressure inside the bellow was varied from 0 to 50 mmHg in increments of 5 mmHg and the corresponding pressure transferred to the weighing scale was calculated. Fig. 4 shows the graph obtained by plotting the pressure inside the bellow against the pressure calculated from the weighing scale.

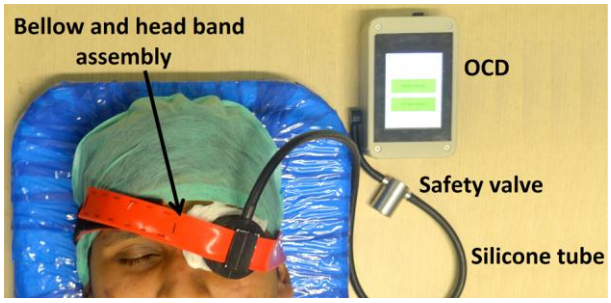

Figure 3. OCD being used on a human subject

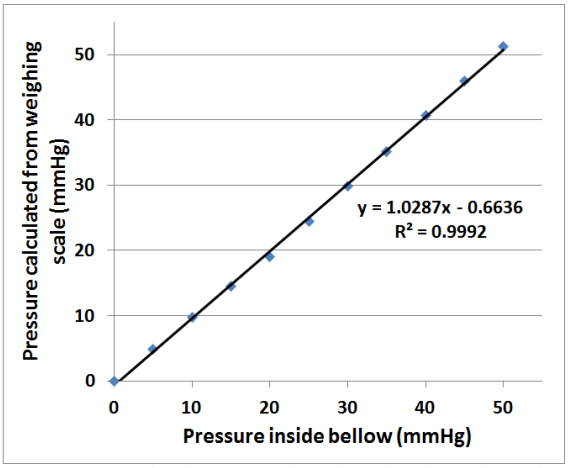

Figure 4. Graphical representation of results of experimental validation of technical functionality

The results obtained validate the fundamental principle of operation of the device. The graph obtained is linear with an R^2 value of 0.9992, verifying that the pressure inside the bellow is approximately equal to the pressure transferred to the eye.

IV. Clinical Validation

In order to determine the efficacy of the developed prototype for reduction of IOP in a clinical setting. a clinical validation procedure was designed and conducted at Sankara Nethralaya. The device details, study endpoints and the clinical trial protocol were presented in a review meeting and an ethics committee approval was obtained prior to clinical trials.

The clinical study end point was to validate the effectiveness of OCD in the reduction of post anesthetic IOP. Patients with history of previous ocular surgeries or glaucoma were excluded from the clinical trials. Written informed consent for the study was obtained from the subjects prior to the trial. Throughout the study, the block, globe compression and IOP measurement were performed by a single non-blinded investigator. All IOP measurements were carried out using a Tonopen®. The protocol followed for clinical validation is given below [8], [9].

- Measure and record baseline IOP.
- Prepare compression device and anesthetic solution.
- Attach pulse-oximeter probe to the patient's finger for monitoring vital signals
- Inject required anesthetic agent after aspiration.
- Measure IOP twice immediately after block.
- Place a piece of gauze on top of the eye. Fasten the bellow on top of the gauze and start compression.
- Upon completion, unfasten the headband. Measure and record IOP twice.
- Record surgeon's grading of effectiveness of globe compression is measured in terms of the softness of the globe as follows:

Grade A: Adequately soft

Grade B: Soft

Grade C: Firm

The clinical trials began with a pilot study to optimize the values of pressure applied, total duration of compression and sample size for the pivotal trials. The pilot study was conducted in two phases. In the first part which included 12 subjects, a qualitative grading of the softness of the eye was obtained from the surgeon after compression using OCD, for various values of compression parameters. The time parameters to be used for the pilot study were finalized from a study conducted on the effect of digital compression on elevated IOP carried out at Sankara Nethralaya [8]. Total durations of two and three minutes were selected. The pressure levels to be applied during the study were fixed at 30 mmHg, 25 mmHg and 20 mmHg. The compression and decompression durations were fixed at 25 seconds and 5 seconds respectively, so as to limit the number of variable parameters. Each pressure and total duration combination was selected as compression parameters for 2 subjects each and the qualitative softness grading of the surgeon was recorded. From this exercise it was concluded that a pressure of 30 mmHg for a total duration of 2 minutes, is most effective in the reduction of IOP.

In the next part, a quantitative measurement of IOP was carried out to fix the sample size to be used in the pivotal trials. The trials were carried out using OCD on 10 subjects, strictly following the clinical study protocol. The compression parameters arrived at from the first phase of pilot study were used. The mean and standard deviation in the reduction of IOP after compression procedure using OCD was found to be 10 mmHg and 3 mmHg respectively. Considering a significance level of 0.05 and a power of 0.9 the sample size needed for pivotal trials was calculated as 25.

In the pivotal trials ocular compression was delivered to 25 patients enrolled for peribulbar anesthesia using OCD, following the clinical study protocol. The compression parameters fixed using the pilot study were used.

V. Result And Analysis

The effectiveness of OCD in reducing IOP was studied both from the quantitative measurement of IOP and the qualitative softness assessment of the globe by the surgeon. Table I gives the summary of the pivotal study results. An increase in IOP was observed for all the 25 subjects after block.

TABLE I. Pivotal Study Results

Sample Size	Baseline IOP (mmHg)		IOP After Block (mmHg)		IOP After Compression (mmHg)	
	Mean	*SD*	*Mean*	*SD*	*Mean*	*SD*
25	16	2	31	3	20	3

The mean values of baseline IOP and IOP after block was found to be 16 mmHg and 31 mmHg respectively. A decrease in IOP was observed for all the subjects in the group after compression procedure using OCD. The mean value of IOP after compression was found to be 20 mmHg. From these results, the mean reduction in IOP after compression using OCD was calculated as 11 mmHg.

Fig. 5 represents the data obtained from the clinical trials using a box and whisker plot for OCD. The bottom and top of the box indicate the 25th and 75th percentile (the lower and upper quartiles, respectively), and the band near the middle represents the 50th percentile (the median). The ends of the whiskers represent the lowest datum still within 1.5 IQR (Interquartile Range) of the lower quartile, and the highest datum still within 1.5 IQR of the upper quartile.

Out of the 25 case studies involving OCD, 21 subjects (84%) were graded A (Adequately soft globe) by the surgeon during the qualitative softness assessment. Out of the remainder, 3 subjects were graded B (Soft) and one subject who was found to have a firm globe even after compression, was graded C (Firm). A graphical comparison of the qualitative assessment of globe softness by the surgeon and the IOP after compression is made in Fig. 6. None of the 25 subjects were presented with lid swelling or conjunctival chemosis after administration of ocular compression using OCD. All 25 surgeries were completed successfully without complications of any kind. Both the qualitative softness grading and the IOP measurements show that OCD is effective in the reduction of post anesthetic IOP.

VI. Conclusion

An air pressure based device that automates the process of intermittent ocular compression with provision to vary the compression parameters was successively developed and validated. The device meets the clinical need addressed and delivers the safety measures required.

The Intra ocular pressure (IOP) measurements in a clinical trial conducted on 25 subjects show that compression using the developed Ocular compression device (OCD) for a total duration of 2 minutes with the pressure set to 30 mmHg resulted in a mean reduction in IOP of 11 mmHg. None of the 25 subjects were presented with complications either due to anesthetic block, compression or the subsequent surgeries. From these observations, the effectiveness, safety and reliability of the OCD were affirmed.

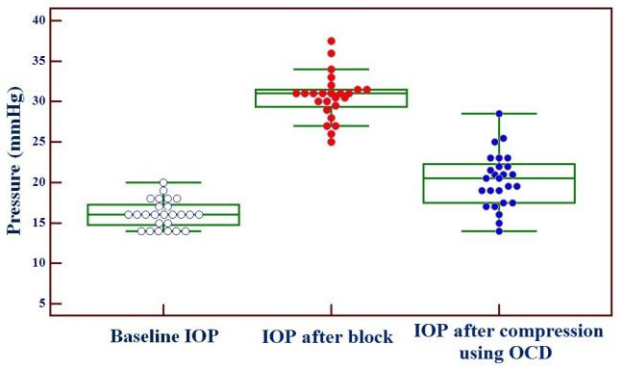

Figure 5. Box and whisker plots indicating Baseline IOP, IOP after block and IOP after compression for the 25 subjects

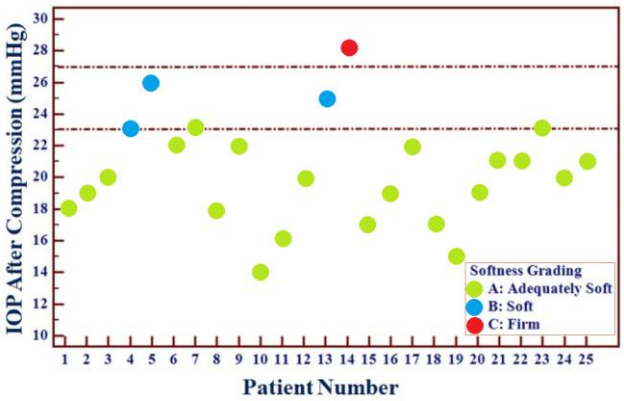

Figure 6. Comparison of the qualitative assessment of globe softness by the surgeon and IOP measured after compression using OCD

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