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A Novel Sclerectomy Technique for Glaucoma and Ocular Hypertension Treatment

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Authors' contributions

This work was carried out through collaboration of all authors. Author ASE designed and implemented the study. Author EA assisted in performing the intervention. Author MMA-Z helped in reviewing the literature and writing. Author MSE helped in writing the manuscript. Author TE-DMO assisted in writing and reviewing the manuscript. Author AM conducted the analysis and wrote the results section. All authors read and approved the final manuscript.

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ABSTRACT

Purpose: To introduce and evaluate the efficacy and safety of a new surgical scleral technique for treatment of glaucoma based on the concept of scleral biomechanics.
Methods: Twelve 3-month-old New Zealand white rabbit eyes were operated under general anesthesia. Single large rectangular full thickness sclerectomy (3 mm limbal x 5 mm) exposing the choroid was performed in each eye. The intraocular pressure (IOP) was measured preoperatively, one day, one week and one month postoperatively.
Results: Twelve eyes of 6 New Zealand white rabbits were operated with sector sclerectomy

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technique. The mean (±SD) intraocular pressure (IOP) was significantly reduced from a preoperative value of 6.0 (±0.0) mmHg to 2.0 (±0.0) mmHg (p = 0.003) in the post-operative assessment. The IOP was quite stable in the following one week and one month follow up assessments at 2.0 (±0.0) mmHg (p = 0.998). Eight out of 12 (66.7%) operated eyes had no postoperative complications. Four (33.3%) eyes faced different complications where: one (8.3%) had corneal perforation by traction suture, 3 (25%) had vitreous loss (one mild and two severe), while one of them (8.3%) had bleeding.

Conclusion: Full thickness sector sclerectomy can change the scleral biomechanical behavior leading to highly significant intraocular pressure reduction.

Keywords: Glaucoma; sector sclerectomy; new glaucoma technique.

1. INTRODUCTION

Glaucoma is the second leading cause of blindness in the world and is estimated to affect about 1 in 40 individuals over the age of 40 years [1]. Meanwhile, glaucoma is a complex multifactorial slowly progressive neuro-degenerative disorder associated with raised intraocular pressure leading to death of retinal ganglion cells and degeneration of their connected optic nerve fibers that would subsequently end up in visual loss.

Till present, no definite cause has been clearly known to explain this condition of progressive optic neuropathy. Although increased IOP is one of the most accepted risk factors causing glaucoma [2,3]. In a recent review of the Ocular Hypertension Treatment Study (OHTS), the most significant risk factors for the development of glaucoma included age, IOP, cup/disc ratio, and thin central corneal thickness [4]. These recent findings have generated increased interest in the biomechanical properties of the ocular coat and its role in the pathophysiology of glaucoma [4].

Characterization of scleral biomechanical properties is important for understanding glaucomatous mechanism of causing damage to the eye. The optic nerve head (ONH) is the principal site of damage in the glaucomatous vision loss pathway. It remains controversial whether the glaucomatous damage is the result of a direct mechanical failure or insufficient vascular perfusion [5,6]. However, it is generally believed that the mechanical environment of the ONH is critical in both mechanisms since it could not only induce direct mechanical loading and deformation of neuron cells, [7] but also mediate the IOP-related blood flow and cellular responses [8]. Since the sclera is the major load-bearing tissue in the eye and the ONH is confined by the peripapillary sclera, scleral mechanical properties could play an important role in affecting the mechanical environment of the ONH [7,9-10].

It is well established that, the chemical architecture of the sclera will determine its biomechanics. Therefore, increased levels of Glycosaminoglycans may be a precursor to a decreased scleral stiffness, whereas under normative conditions, collagen content and architecture have been implicated as primary determinants of stiffness. Consequently, it achieves superior stiffness via increased collagen cross-links density [11].

The aim of current glaucoma treatment modalities is to preserve the visual function via achieving a within-normal IOP along with minimal possible side effects (efficacy and safety). Thus, effective management of glaucoma requires achieving of a reduction of intraocular pressure to the most appropriate level for the stage of disease.

Moreover, in the last decade, intensive research work has been conducted in evaluation of glaucoma surgery. When conventional methods fail, patients can be well served by innovative new surgical techniques, especially, non-penetrating glaucoma surgery which is also known for being minimally invasive. These new techniques clear the way for restoring fluid passage through the eye. These infrastructure improvements are essentially extra-ocular techniques which have much improved surgical success rate with minimum postoperative complications. Within this context, comes the idea of dealing with the biomechanical and biochemical properties of the sclera either surgically or chemically.

Total sector sclerectomy is our proposed novel technique which is aiming to change the biomechanical effects of the sclera on the eye. There is a need to evaluate this technique in terms of both its efficacy in reduction of the IOP and safety in terms of the frequency of postoperative complications.

2. METHODS

Six New Zealand white rabbits were obtained from the local abattoir; all rabbits were between 2 to 3 month old and weighting between 1.5 to 2 kg. During the study, rabbits were kept in suitable place and marked numerically.

All procedures were performed in accordance with The Association for Research in Vision and Ophthalmology (ARVO) Statement for the Use of Animals in Ophthalmic and Vision Research.

Twelve eyes were operated, while only eleven eyes were completed. Each rabbit was anesthetized using a combination of intramuscular ketamine and xylazine (ketamine 40 mg/kg; xylazine 20 mg/kg) and topical anesthesia (2% lidocaine gel) before initiation of surgery. Baseline IOP was measured with both a hand-held corneal applanation tonometer with an accuracy of ±2 mm Hg (Perkins Mk 2, Clement Clarke International) and schoitz tonometer. Operations were done using Leica ophthalmic microscope (Leica microsystems, Germany). Surgeries were done under total sterile conditions. A 5 mm x 7 mm superior periotomy was performed with no cauterization needed. We fashioned large rectangular full thickness sclerectomy (3 mm limbal x 5 mm) exposing the choroid. Conjunctiva was closed using 8/0 vicryl Figs. 1-3. After each operation, IOP was measured in the 1st and 3rd postoperative days and then weekly over a month.

2.1 Statistical Methods

Data were collected and stored in a spreadsheet using Microsoft Excel 2010® software. Data management and coding were both done in excel. Data were analyzed using SPSS® version 20.0 (*IBM* Inc., Chicago, Illinois, USA).

Descriptive analysis was done, where categorical variables were presented as frequencies and percentages and continuous variables as mean and standard deviation (±SD). Inferential analysis was done where Wilcoxon Signed Rank test was used to test the difference between pre- and post- operative IOP assessments. Confidence interval level was set to 95% where a corresponding *p* value threshold was identified as 0.05. Accordingly, *p* values <0.05 were interpreted as denoting statistical significance.

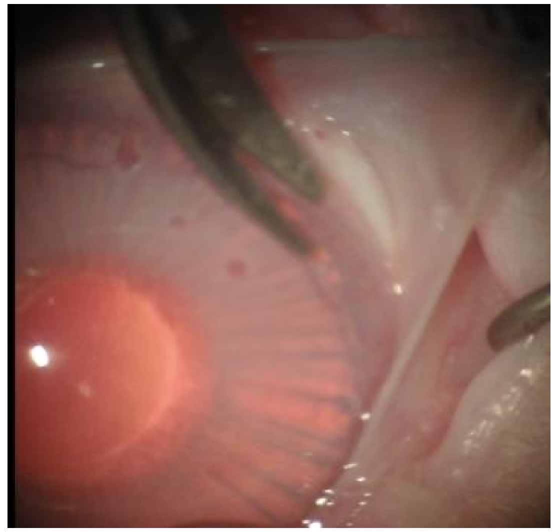

Fig. 1. Conjunctival dissection

Fig. 2. Scleral dissection using crescent knife

3. RESULTS

Twelve eyes of 6 New Zealand white rabbits were operated with sector sclerectomy technique. Surgery was completed to its potential end in 11/12 (91.7%) eyes, while only one eye was incomplete. The mean (±SD) intraocular pressure (IOP) was 6.0 (±0.0) mmHg in the preoperative assessment. One day postoperatively, the mean (±SD) IOP has significantly decreased to 2.0 (±0.0) mmHg (*p* =

0.003). The IOP was quite stable in the following one week and one month at 2.0 (±0.0) mmHg (p = 0.998). Eight out of 12 (66.7%) operated eyes went without any postoperative complications. However, 4 (33.3%) eyes faced different complications as follows: one (8.3%) had corneal perforation by traction suture, 3 (25%) had vitreous loss (one mild and two severe), while one of them (8.3%) had bleeding.

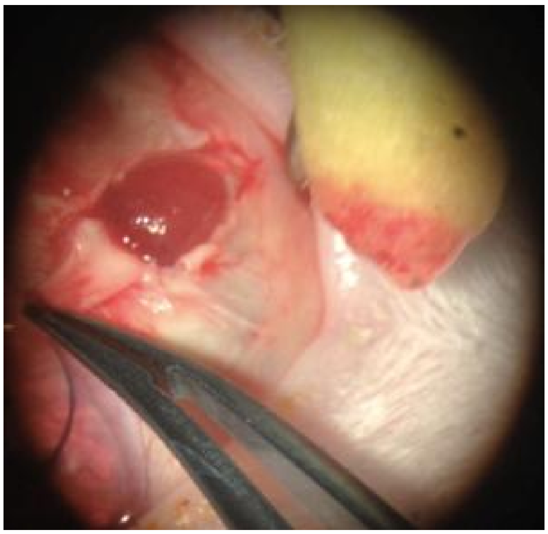

Fig. 3. Exposed choroid after total sector sclerectomy

4. DISCUSSION

Currently, the sclera is gaining its own growing importance as one of the main reasons of glaucoma. Several previous studies have discussed the biomechanics of the sclera and how these properties have direct effect over the optic nerve head biomechanics which in its turn damage the optic nerve at the level of lamina cribrosa. The ONH biomechanics are strongly dependent on scleral biomechanical properties. This suggests that inter-individual variations in scleral properties could be a risk factor for the development of glaucoma [12-14]. Eye size and lamina cribrosa biomechanical properties also have a strong influence on ONH biomechanics. Scleral deformations are transmitted to all ONH tissues. Consequently, any factor that would change the response of the sclera to IOP (such as scleral stiffness) would have a potentially large influence on ONH biomechanical behavior. These findings strongly suggest that scleral biomechanical properties, particularly those of the peripapillary sclera, may play an important role in the biomechanics of glaucomatous optic neuropathy [12-14].

This hypothesis reinforces our belief that we might require better measurements of scleral biomechanical properties. The determinants of scleral mechanical properties are the content and architecture of structural proteins. Glycosaminoglycans (GAGs) and collagen type I are proteins known to be most influential in determining how the sclera responds to load [11]. Meanwhile, both enzymatic and non-enzymatic cross-links accumulate with age. Therefore, further work is also needed to quantify all types of cross-links that are present in various scleral models.

It is quite clear that biomechanical and biochemical properties of the sclera play a significant role in glaucoma pathogenesis. Thus, the question now is how to change the effects of these properties on the globe in order to stop the pathogenesis of glaucoma. Consequently, in this study we focused much on scleral biomechanics.

We hypothesized that the intact sclera works as one unit sliding over the choroid because of the suprachoroidal potential space. So, we proposed that full thickness scleral incision will interfere with the integrity of the sclera, leading to direct changes in its behavior. Accordingly, we fashioned large rectangular full thickness sclerectomy (3 mm limbal x 5 mm) exposing the choroid to prove our hypothesis. The results were very promising as significant reduction in intraocular pressure was achieved over the follow up period. In the first day of our postoperative assessment, the IOP significantly reduced from 6 mmHg to 2 mmHg and such reduction was maintained during the first month without any significant increase. This would provide evidence on efficacy and stability of such reduction.

Our theory to explain this intraocular pressure reduction is that the sclerectomy does not change the biomechanics of the sclera but it acts like a release incision that will reduce the effect of the stiff sclera over the globe, which probably increases the suprachoroidal potential space hence increasing the uveoscleral out flow.

The major disadvantage of this technique is that it may cause some fragility in the eye. Removing part of the sclera will make the choroid and the inner structures of the eye only protected by the conjunctiva. However, this disadvantage may potentially be handled. Overall, the size and shape of sclerectomy will indicate how fragile the eye will be. Therefore we are looking forward to identifying the ideal sclerectomy to be performed in terms of size, shape and site. Long-term follow up will show how much the fibrosis will be over the choroid and if it is going to overcome this fragility problem. It is also open for researchers to find ways to shield the sclerectomy site. Comparing eye fragility of this surgery with eye fragility of trabeculectomy safety will be in favor of our surgery. The issue of safety and lower frequency of complications was also in favor of deep sclerectomy versus trabeculectomy and combined trabeculectomy trabeculotomy in many comparative studies that were concerned with comparing the two common procedures since the early 2000's [15].

Further studies with larger sample size, longer follow up durations, and phase II & III trials are certainly needed to cover many different aspects and enable more room for improvements. Additionally, further modifications of the sclerectomy size will take place in some other coming studies as we need to figure out the smallest possible size of sclerectomy which would give the same effect. Moreover, site of sclerectomy will be tested whether to be anteriorly or posteriorly done as the peripapillary sclera is the part of the sclera that directly affects the optic nerve head biomechanics. Nevertheless, potentially associated risk factors such as severity, type of glaucoma and other factors will be investigated to determine its contribution in IOP reduction and success / failure of surgery as well as the frequency and type of complications. There is also a crucial need to carefully evaluate the optic nerve head biomechanics pre- and post-operatively in addition to measuring the suprachoroidal space. A well-equipped lab along with other advanced facilities is required to enable more sophisticated investigations and provide more reliable results.

5. CONCLUSION

Full thickness sector sclerectomy can mediate significant IOP reduction. Change the scleral biomechanical behavior leading to highly significant intraocular pressure reduction.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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