

Assessment of a software guided system to reduce pre-existing astigmatism in cataract surgery

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The aim of this pilot study was to assess the astigmatism after small incision cataract surgery by use of a novel software guided surgical technique. The software system guides the surgeon toward a hypothetical shape of the cornea. When this shape is achieved, the vertical meridian is relaxed and the incision does not produce any astigmatism. How that hypothetical shape is to be achieved by the surgeon is described. If preoperative astigmatism exists, the hypothetical shape calculated by the system takes that into account. This enables the surgeon to reduce preexisting astigmatism, without having to change the site or size of the standard 6 mm 12 o'clock incision of SICS. Results: Results indicated that preoperative astigmatism reduced in 11 out of 14 cases at the end of 8 weeks, remained unchanged in one, and increased by less than 0.5D in two cases. This proves the hypothesis that the vertical corneal meridian is under higher tension and relaxing it by flattening the perpendicular meridian has a reducing effect on postoperative astigmatism.

Key words: Astigmatism, cataract, k2k system, SICS

Cataract surgery aims to give the best possible spectacle free vision to the patient. Astigmatism is a cause of poor uncorrected postoperative vision.^[1,2] Currently used ways to reduce induced astigmatism or correct astigmatism are limbal relaxing incisions, use of toric lenses, and laser corrective procedures on the cornea, changing site or size of incision.

A superior incision during cataract surgery causes more astigmatism as compared to the temporal or supero-temporal incision.^[3] Hooke's law of elasticity states that deformation caused in the tissue on incising it will be directly proportional to the tension in the tissue.^[4] The vertical corneal diameter is less than the horizontal diameter. Therefore, it was hypothesized that the tension in the vertical corneal meridians is higher than tension in horizontal meridians. Gauss's theorem egregium and the work of Dr. Alpains tells us about the coupling effect which states that tension in a meridian can be reduced by flattening the meridian perpendicular to it.^[5] To validate our hypothesis, a handheld keratoscope was used. It was held in the hand under the microscope, and mires were repeatedly checked. The horizontal meridian of the cornea was stretched before taking the superior incision by injection of viscoelastic in the eye, in order to relax the vertical meridian. Results were encouraging and induced astigmatism after taking incision in the vertical meridian reduced substantially. This data was presented in the ISMSICS World conference in Chennai, India in December 2017. Encouraged by these results, the K2K system was developed. The algorithm was

developed to reduce preexisting astigmatism, and to steepen the vertical meridian sufficiently before incising it, so as to not cause the flattening of the vertical meridian because of the incision itself. [Fig. 1].

Methods

Patients with cataract presenting to our hospital were examined in detail. Inclusion criteria were those with diagnosed senile cataracts. Patients with relevant other eye disorders such as pterygium, prior corneal surgeries, corneal scars, moderate and severe keratoconus were excluded. Sixteen consecutive patients were included in the study and were operated on by the same surgeon using the k2k system. Ethics committee permission, as well as informed written consent, was taken. Follow up was done at 8 weeks postoperatively. Two patients were lost to follow up at 8 weeks and were excluded. Preoperative and postoperative astigmatism was measured on the same IOL master.

Description of the K2K system

A self-illuminated keratoscope is mounted on the operating microscope. The keratoscope is 3D printed and mounted with medically safe certified, brightness adjustable LED's (light-emitting diodes) in two concentric circles. The outer circle of the LED's image represents the central 2.5 mm of the cornea. [Fig. 2]

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A user interface allows entering the unique identity of the patient and preoperative keratometry readings. A video camera attached to the microscope captures the images of the eye along with the image of the LEDs in the keratoscope. These images and data entered are transmitted to a remote server via the internet. The server is written in python programming language to process data being transmitted to it from a surgeons graphical user interface and transmit back data to the same.

The server hosts a machine learning module that detects and processes the images of the keratoscope. Using this data an algorithm continuously suggests the existing long axis of the image of the keratoscope on the cornea and the intended long axis of the image of the keratoscope on the cornea to be achieved by the surgeon. When the surgeon manipulates the cornea to reach the intended axis as described in step two of surgical methods, it would result in a spherical cornea postoperatively with a six mm incision centered at 12 o'clock.

This process continues while the surgeon manipulates the cornea to achieve the intended shape and continuous image and audio inputs are given to the surgeon.

Scientific basis of the algorithm

[Fig. 3] Cornea is under stretch in the vertical meridian, because of the inherent short vertical diameter^[6] When the cornea is incised in vertical meridian, it causes a flattening of 1.25 D similar to the gaping seen in the vertically stretched balloon in [Fig. 3a].^[1] The algorithm calculates the vector forces acting on the vertical meridian, and then indicates which meridian must be stretched to relax this tension. Additionally, an astigmatic cornea is stretched in the direction of the flat meridian. The resultant stretch in the cornea is a combination of the two vectors and can be calculated by using the parallelogram law of forces.

The vector will be along the diagonal as shown in the [Fig. 4c]. If a meridian perpendicular to the resultant vector is stretched, the vertical meridian will relax and should not gape on incision.^[2]

The algorithm calculates this by the following steps. The vector A is 1.25 dioptres for a spherical cornea. The preoperative keratometry readings are fed into it, to know vector B. Changes induced by the tunnel itself, before entry are measured by the initial reading of the online keratometer, and added to the vertical vector A. Parallelogram law of forces is used to know the resultant vector, its angle and magnitude. The meridian perpendicular the resultant vector is calculated and informed to the surgeon as "intended meridian" in which the surgeon must stretch the cornea before taking the entry incision as well as before extending the entry incision. The method of stretching is described in the section Surgical Technique.

Keratometric measurements are done before the construction of the tunnel to assess the cornea in its virgin state. Keratoscopic measurements are then performed real time after the construction of the tunnel but before the entry into the anterior chamber taking into account the change in the cornea by making the tunnel thus taking into account the change in the stretch in the cornea after the tunnel has been made. To take into account cyclorotation of the eye keratoscopic measurements are analyzed to find the steepest and flattest meridians. They are then compared to the preoperative keratometry readings. For example, consider that the flat axis

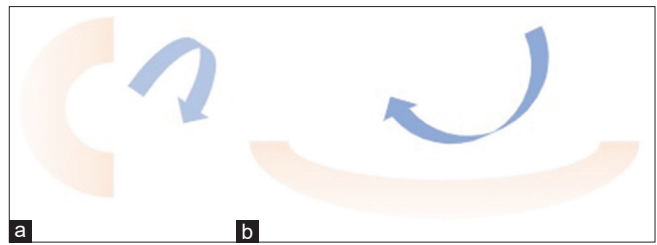


Figure 1: (a) Vertical schematic cross section of cornea – tightly bent cornea. (b) horizontal schematic cross section of cornea – gently bent cornea. Measurements have been exaggerated to explain that there is a higher tension in vertical meridians of the cornea. Vertical corneal diameter is less than horizontal corneal diameter^[7]

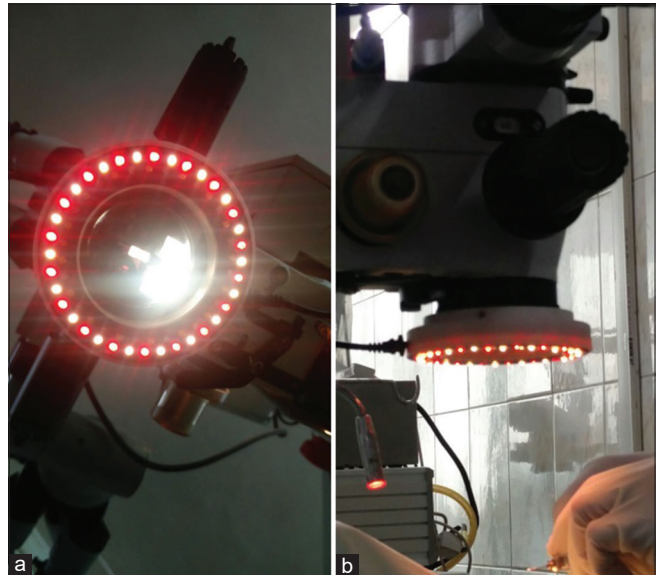


Figure 2: (a) Keratoscope turned on – patient view (b) Keratoscope mounted on microscope turned on – lateral view

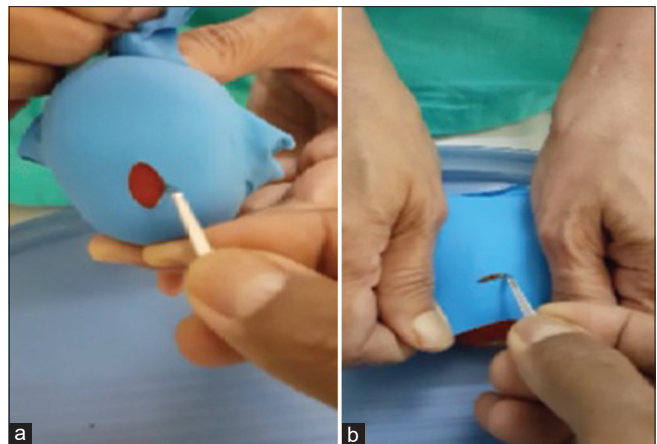


Figure 3: (a) Horizontal incision is taken in a vertically stretched balloon, to show how there is a vertical gape. The vertically stretched rubber tears vertically on incising it horizontally, as per Hookes law of elasticity. (b) Showing how the same balloon, when it is horizontally stretched, and incised in the same way, does not cause gaping in vertical direction

in the preop keratometry analysis is 90 degrees and the flat axis from online keratometry reading at the time of pressing

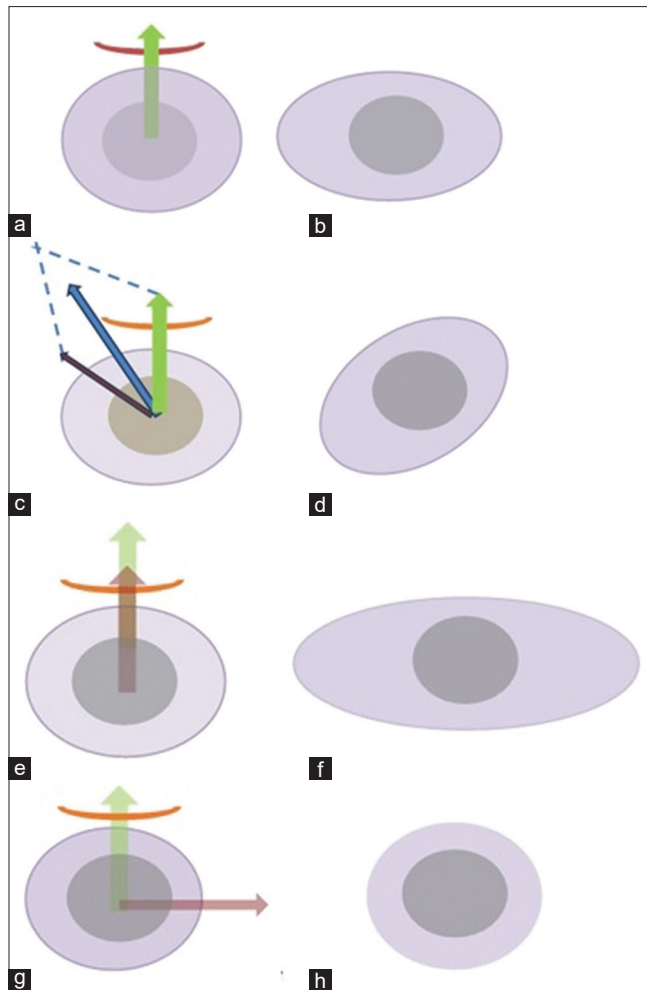


Figure 4: (a) Stretched spring like force acting on a perfectly spherical cornea owing to shorter vertical diameter. Green arrow. (b) System will ask for creation of this corneal shape in order to relax the spring like force on vertical meridian by flattening the horizontal meridian. (c) Resultant spring like force blue arrow in a cornea with pre existing minus cylinder at 135 degrees, calculated by the algorithm using parallelogram law of forces. (d) System will ask for creation of this corneal shape in order to relax the spring like force on oblique meridian by flattening the oblique meridian perpendicular to the resultant force (e) Resultant spring like forces in the cornea with pre existing minus cylinder at 90 degrees. (f) The algorithm indicates much more stretching of the horizontal meridian to relax the vertical meridian. (g) Resultant springlike forces in a cornea with pre existing minus cylinder 1.5 D at 180 degrees (h) The algorithm indicates preservation of the corneal shape as it is at the moment of incision

the freeze button is 85 degrees. The eye is then considered to be cyclorotated by 5 degrees and the difference is factored into the calculations. [Fig. 4]

Surgical technique

Anesthesia: Topical and pinpoint anesthesia.^[7] A 6 mm mild frown scleral tunnel incision centered at 12 o'clock is taken 1.5 mm behind the point of conjunctival insertion on the sclera measured at 12 o'clock. The tenon is identified and managed as a separate tissue plane.

After the construction of the tunnel, but before entry into the anterior chamber, the online self-illuminated keratoscope

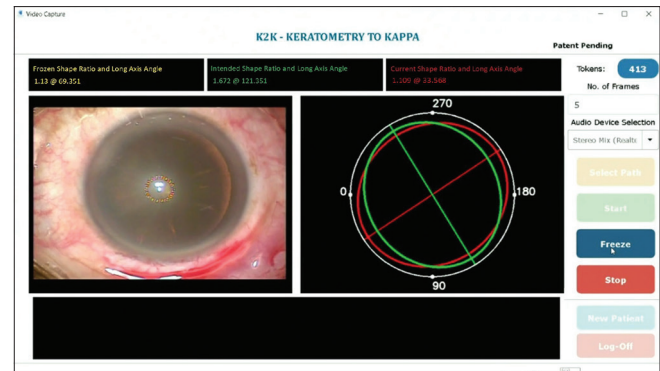


Figure 5: Left: Analyzed microscope view with the reflection of the keratoscope LED's. Right: Response image returned by server. Dynamic red ellipse depicts the current shape of the detected keratoscope. This changes continuously based on the pressure on the posterior lip of the incision at the time of entry into anterior chamber and the stretch in the cornea created by injection of viscoelastic prior to extension of incision. Longest axis depicted by red line. This denotes the flattest axis currently directed. Fixed green ellipse depicts the intended shape drawn by the algorithm. Longest axis depicted by the green line. The aim of the surgical manipulations is to make the red and the green line superimpose. White circle denotes the central 2.5 mm of cornea

is turned on. The patient is asked to fixate on the microscope light and the freeze button is pressed which starts the analysis process. [Fig. 5].

For the initial entry into the anterior chamber, a keratome is placed at the site perpendicular to the intended axis. Without any inward pressure, posterior pressure is applied to the bed of the tunnel by the blade of the knife. The surgeon understands from the audio whether the current axis is moving closer to the intended axis or not. If the current axis is within 20 degrees of the intended axis, the entry incision 1.5 mm in length is taken. If the current axis is not close to the intended axis, two further steps are taken [Fig. 2]. First, additional external pressure is applied to the limbus by corneal forceps held in the other hand. Second, the site at which the posterior pressure is being applied by the knife is changed. By varying the selection of site, amount of posterior pressure, and external pressure, the current axis is superimposed on the intended axis, and then entry into the anterior chamber is made to create a 1.5 mm incision.

The 1.5 mm incision is used to inject methylcellulose into the anterior chamber at selected locations anterior to the iris, with boluses being injected at the two poles of the intended long axis.

When anterior chamber is filled with aqueous, the aqueous, being a homogeneous fluid causes uniform pressure on the posterior surface of the cornea, and as per pascals law of partial pressures, the pressure exerted in all directions is equal per every unit surface area of the posterior cornea. However, when methylcellulose is injected in boluses in specific regions of the anterior chamber, it does not immediately spread all over the anterior chamber because of its viscous properties, and therefore it stretches the horizontal meridian if injected in horizontal meridian anterior to the iris in boluses. The stretching effect lasts for a few minutes, which is enough to execute the incision.

Care is taken not to allow the injected boluses to leak towards the center of the pupil. No methylcellulose bolus is

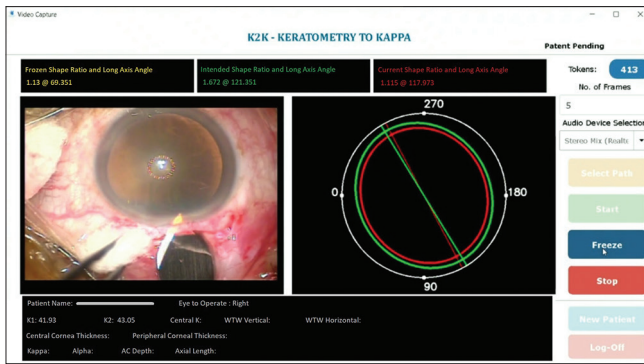


Figure 6: After the manipulation described above, the red line indicating the current long axis of the keratoscope image is perfectly aligned with the green line which depicts the intended long axis drawn by the algorithm

Table 1: Post-operative astigmatism outcomes

Eye	Pre op astigmatism	Post op astigmatism	SIAref.
OS	1.12 × 123	0.61 × 136	0.63
OS	0.29 × 98	0.12 × 85	0.19
OS	0.32 × 72	0.22 × 132	0.46
OD	0.99 × 84	0.54 × 92	0.49
OD	1.12 × 102	1.04 × 101	0.09
OS	0.49 × 110	0.49 × 100	0.17
OS	0.25 × 164	0.31 × 104	0.49
OD	1.16 × 95	1.03 × 137	1.47
OS	1.14 × 107	0.41 × 69	1.11
OD	0.32 × 167	0.45 × 130	1.05
OD	1.5 × 70	1.61 × 88	0.97
OD	1.23 × 33	0.7 × 92	1.68
OD	1.91 × 81	1.61 × 88	0.52
OS	0.48 × 42	0.32 × 64	0.33

*SIA - Surgically induced astigmatism, Re - Right eye, le -left eye

injected in the long axis of the current corneal shape. To extend the incision, a 5.2 mm keratome tip is placed into the initial entry incision through the sclero corneal tunnel. Posterior pressure is applied. If the current long axis is not aligned with the intended long axis by use of pressure alone, external pressure with corneal forceps and tilting of the blade while maintaining the posterior pressure is attempted. Extension of the incision is made by a single inward stroke when the intended long axis and the current long axis were within 20 degrees of each other. The lateral 0.5 mm extensions of the incision are made without software control.

The further steps in small incision cataract surgery viz. capsulorhexis, nucleus removal, irrigation aspiration of the cortex, capsule polishing implantation of an IOL, removal of viscoelastic and closing the incision by a tenon cover as well as a conjunctival cover were done as usual.

IOL power calculations were not altered in any way. [Fig. 6]

Results

Table 1 Out of the 14 cases included in the pilot study, astigmatism reduced in 11 cases and was unchanged in 1 case.

In the two cases that the astigmatism increased, it increased by 0.15 and 0.11 diopters.

Discussion

Out of the 14 cases included in the study, 9 were having preoperative astigmatism in vertical meridian. (70 to 110 degrees). Even though the incision was six mm at 12 o clock, astigmatism reduced in 8 out of these 9 cases. Considering previous publications,^[1] it was expected that astigmatism would have increased by 1.29 diopters in each of these cases. But it did not. None of the cases had zero postoperative astigmatism. In two cases, postoperative astigmatism increased. This may be due to certain drawbacks in the system.

Drawbacks in the system: The algorithm uses average values of vertical and horizontal diameters as well as average values of corneal thickness. Precise preoperative measurement of these variables may improve outcomes. The system has a learning curve.

The system may not help the surgeon to reach the correct end point in cases of corneal disease or degeneration, where an image of the keratoscope is difficult to obtain.

Conclusion

Our pilot study shows reduction in astigmatism in 11 out of 14 cases and no change in astigmatism in 1 case, performing the fixed six mm vertical meridian incision, after relaxing the vertical meridian. This proves that vertical corneal meridian is under higher tension and relaxing it by flattening the perpendicular meridian has a reducing effect on postoperative astigmatism. A statistical study with a larger sample is required and is underway. Further improvements in the algorithm with reference to corneal diameter measurement and corneal thickness may ensure even betterment of outcomes.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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