

**Topographic Aberrometric Guided Customized Surface Ablation TAGCA with
simultaneously accelerated Riboflavin/UVA cross-linking as a treatment method for
progressive Keratoconus.**

“Emirates Protocol“

Dr. Safwan Al Bayati, FRCS (Glasgow), FICMS, MBCHB

New Vision Eye Center, Dubai, United Arab Emirates

Corresponding Author:

Dr Safwan Al Bayati, FRCS FICMS OPHTH

Medical Director

New Vision Eye Center

Tel: +971 4 51 9595

Fax: +971 4 451 9696

Mobile: +971 50 896 6019

www.newvisioneyecenter.ae

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Abstract

Purpose: To evaluate the effectiveness of TAGCA using Schwind AMARIS and ACXL in single procedure for KC treatment.

Setting: New Vision Eye Center, Dubai, UAE.

Design: Prospective study to evaluate new guidelines for PRK laser in KC.

Method: All progressive Keratoconic eyes underwent trans epithelial TAGCA PRK using Refractive module able to incorporate the corneal wavefront selecting coma, spherical aberration, and trefoil with patient's refractive error taking into consideration*Optical zone is related to cone's outer-border *Corneal thinnest point is not less than 300 μm post-op*The degree of patient's sphere and cylinder chosen depending on the patient's corneal thinnest point, corneal map cylinder/axis. Inclusion criteria: *Clear cornea no hydrops* Pachymeter is equal or thicker than 400 μm * K reading is less than 60D. Followed by ACXL. Pre & Post-Op evaluations include: manifest refraction, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), topo-tomographic corneal map with minimum follows up of 12 months.

Results: This study comprised 30 eyes of 30 patients ranging in age from 17 to 35 years. UDVA mean improved from 20/100(0.7 logMAR) to 20/40 (0.3 logMAR) with P value =0.02, CDVA mean improved from 20/55(0.4 logMAR) to 20/30(0.1 logMAR) with P value= 0.01. All eyes showed remarkable improvement in corneal wavefront.

Conclusion: TAGCA PRK through its Refractive module of High Order aberration management in Schwind's AMARIS treatment profile followed by ACXL is safe and effective therapy that regularize the ectatic corneal surface, improve the visual function of progressive in KC without over correction nor increase of existence myopia,

Introduction

Keratoconus is a disease of corneal collagen that characterized by progressive corneal thinning resulted in corneal protrusion, irregular steepening, flattening, myopic astigmatism, and large value of corneal high order aberration (coma, spherical aberration, trefoil) that leads to decrease the vision through reducing the contrast sensitivity and through an irregular myopic spherical equivalent which consequently resulted from the protrusion.¹

In early stages of KC eyeglass can rehabilitate visual function with progression of disease and increasing of high order aberration (HOA) (coma), the patient will become more intolerant to eyeglass. At this point RGP will be very helpful in improving the visual acuity because of its ability to suppress the corneal high order aberration and treat the spherical equivalent. This makes RGP superior to eyeglass.¹ When KC advances, the irregular corneal shape is no longer be fit with a contact lens. Intra stromal corneal ring segments has been proposed as a method of regularizing the corneal shape in association with Riboflavin/UVA Cross-linking^{2,3}. Although it is effective in many patients, some eyes still have sufficient irregularity limiting the full potential return of corrected vision. Keratoplasty must be considered to rehabilitate visual function. Riboflavin/Ultraviolet (Corneal Collagen Cross-linking) (CXL) has been shown effectively halt the progression of KC and in some cases gradually reduces the refractive and Keratometry irregularity.^{4,5,6}

Although CXL is proven to halt the progression of KC, it has no effect in improving or restoring the irregularity of corneal shape to rehabilitate the visual function of the patient^{5,6}. Cross-linked corneal patient with considerable visual acuity can benefit from ICL to rehabilitate their visual acuity, but if patient's corrected visual acuity was very poor and patient was intolerant to RGP lens. ICL in this situation will not be able to correct the whole irregularity (HOA& SEQ)^{7,8}. Hence the need for further refractive correction is required; topography guided photorefractive Keratometry (PRK) has been proposed as palliative method for correcting irregular astigmatism in KC.^{9,10,11} However the progression of

weakened cornea structure in the absence of CXL was a major concern for all surgeons because of the risk of ectasia progression after laser treatment.^{9,10,11} In 2010, Prof. Kanellopoulos published many articles that started a new way in KC treatment. The Athens Protocol which includes treatment of corneal irregularity by using Topography Guided PRK Trans Epithelial Photorefractive Keratectomy (PTK 50 μ m constant epithelial thickness and optical zone 6.50 mm) followed by refractive laser with optical zone of 5.50 mm and 70% cylinder and sphere upto 50 μ m central depth using T-CAT module of Allegretto Wave Eye-Q Excimer laser (Alcon Laboratories Inc), this laser treatment is immediately followed by CXL. The concept of both regularizing the cornea irregularity and strengthening the weakened corneal stroma by CXL which in return its effect appear to be more when it preceded by laser and the use of CXL after the laser showed the

reduction of corneal stroma haziness¹²⁻¹⁸. This synergetic action, which is proved by Prof. Kanellopoulos, was one of the most important events in KC treatment.

In this study, our team at New Vision Eye Center/ Dubai and with Algorithmic Team of Schwind's AMARIS Company needs to introduce a new protocol using same synergetic action of laser and ACXL, both at one session but using topographic aberrometric guided customized ablation trans epithelial PRK laser. The treatment profile of this laser is guided by corneal wave front (corneal HOA) which is derived from the corneal elevation map incorporated into Zernike Polynomials. This way the corneal elevation map can be read by term of Zernike 7th order using Sirius (CSO, Italy) corneal map which uses Placido- Scheimpflug technology (topo-tomographic picture). The selection of the best corneal topography map depends on the acquisition which comprise of Scheimpflug images coverage centration percentage, and Placido- disc images coverage centration percentage. Both should be above 90%-80% respectively. Each corneal image is a mean of 25 images taken in 5 seconds by Sirius. This device is in conjugated with AMARIS 750s excimer laser machine. The data from Sirius will be transferred into the software of AMARIS which in turn will transform the aberration data into an adequate ablation profile. In the treatment's profile software, the corneal HOA can be managed through two modules (Refraction module, and Pyramid module).

The Refraction module selects automatically the refraction which is most appropriate to save tissue, either in depth or in volume, within the selected constraints. The surgeon can open those constraints so that the software picks up any refraction within the entire refractive ranges which saves the most tissue. If the constraints are used, either for sphere or cylinder and axis or all together, the chosen refraction is the most effective one within the selected constraints. By default the constraints are 0.88 D for the sphere and 0.63 D for the cylinder and 8° for the axis which in summary are 1.25 D in the spherical equivalent.

As this topics deals with highly aberrated eyes the determined pre-op refraction is very uncertain and masked by the influence of the HOA. The surgeon has the ability to choose any residual refractive error according to the patient's error. This reflects also the possibility to consider the flattening effect due to the CXL procedure. This selective ability of the Refractive module in its treatment profile gives us the ability to reach an optical zone upto 8mm without creating any over correction. The Pyramid module allows the surgeon to select the most significant HOA by himself or following the software proposal which individually selects the HOA which contribute to save further tissue. Herein, we evaluate the effectiveness and stability of simultaneous trans epithelial Topographic Aberrometric Guided Customized PRK with ACXL 18mW/cm² as a method of regularizing the cornea and strengthening the weakened corneal stroma collagen.

Materials and Methods:

1-Patient's Selection:

All 30 eyes have been seen by the author Dr. Safwan Al Bayati at his private practice (New Vision Eye Center). Once a diagnosis of progressive KC is confirmed by corneal map and KC screening map, which includes progression of myopic refractive error with or without progression of manifest astigmatism, decreasing uncorrected and corrected visual acuity, progressive inferior corneal steepening on topography, and/or decreasing inferior corneal thickness; all optional modalities of KC treatment are discussed with the patient. Starting from CXL followed by RGP lens, CXL followed by ICL if the patient's CDVA is accepted by him or her. If patient's CDVA was very poor or patient was intolerant to contact lens, then the option of Keratoplasty and its complications will be discussed. If the patient is reluctant to do any of these modalities and he/she was within our criteria:

Inclusion criteria:

- 1- Clear cornea no hydrops.
- 2- Pachymeter is equal or thicker than 400 μ m.
- 3- K reading is less than 60D.

The patient will be presented with the option of Emirates Protocol "Trans Epithelial Topographic Aberrometric Guided Customized PRK simultaneously with ACXL" as a possible technique to prolonger or prevents the need of Keratoplasty. All patients provided written consent prior to undergo the combined treatment.

2- Surgical Technique:

Emirates Protocol: Emirates Protocol consists of these steps:

Step 1: Trans epithelial laser 55 μ m central, 65 μ m peripheral.

Step 2: Topographic aberrometric customized guided PRK laser:

-The amount of sphero-cylinder that will submitted by the surgeon will be in consideration to the thinnest central corneal point, which should not reach less than 300 μ m after laser, and the optical zone should cover the outer border of cone using

the tangential map and placing the arrow on the outer border of the cone. The map will give the location of that point from the pupil center. The distance between the pupil center and the geometrical center will be added to it. The result will be half diameter of the optical zone.

-Corneal HOA that derived from corneal topography on an area covering the outer border of the cone will be transferred automatically to the refraction software.

Step 3:

The Refractive module of HOA management will receive automatically:

-Sphero-Cylinder amount with its axis, and the optical zone size submitted by the surgeon.

- HOA from Topo-Tomography.

- The Refractive module has the constraints which is side blank has default of 0.88D sphere, 0.63D cylinder and 8 degree axis variant. These defaults can be changed by the surgeon according to the need of refractive error residual desired to prevent over

correction that can be induced by the flattening effect of the ACXL. This refractive residual value which reflects the ACXL ability to flatten the cornea, appears to be more effective when it proceeded by laser.

The Refractive module software will analyze all these information through 5 steps, and will give us the final sphere-cylinder-axis-amount of HOA, and refractive residual results. These final results are reflection of an algorithmic incorporation between the refractive error, and the cornea HOA in order to save as much corneal tissues as possible.

- Post laser: Mitomycin-C in a concentration of 0.02% for 20 seconds.
- Followed immediately by ACXL by integrated Schwind CXL-365 Vario system (Schwind AMARIS 750s equipped with Schwind CXL-365 Vario system) (Figure1).

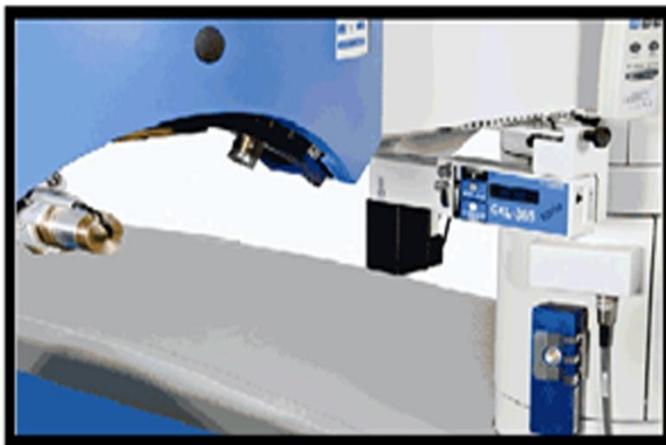


Figure 1: Schwind AMARIS 750s laser machine equipped with ACXL Vario system.

a- If the cornea's thickness after the surface ablation was more than 400 μm then CXL Isotonic Riboflavin Dextran 500 was applied topically every 2 minutes for 20 minutes then emitting UVA light of mean 365-nm wavelength and $18\text{mW}/\text{cm}^2$ radiance at 2.5 cm was projected onto the surface of cornea for 5 minutes. **b-** If the cornea's thickness after the surface ablation was less than 400 μm then CXL Isotonic Riboflavin Dextran 500 was applied topically every 2 minutes

for 10 minutes then Hypotonic Riboflavin Dextran 500 every 2 minutes until reaching 400 μm , then emitting UVA light of mean 365-nm wavelength and $18\text{mW}/\text{cm}^2$ radiance at 2.5 cm was projected onto the surface of cornea for 5 minutes.

-Bandage Contact Lens (BCL) was placed on cornea upon the completion of combined procedures. It is advised to protection natural lights with using sunglass.

-All eyes have been treated with topical antibiotics (Vigamox 0.5%; Alcon Laboratories, Inc, Fort Worth, Texas, USA, and topical steroid (Econopred 1%); Alcon Laboratories, Inc, Fort Worth, Texas, USA) for 4 weeks in a tapering way(4 times /day/1st week,3 times /day/2nd week,2 times /day/ 3rd week, 1 time/day/4th week).

-Vitamin C 1000mg (once daily) for 1 month.

-Artificial tears 6 times per day for 3 months.

- BCL was removed after 5-7 days following complete re-epithilization.

The following evaluations were completed before and after both treatments: age, sex, uncorrected distance visual acuity(UDVA), corrected distance visual acuity (CDVA), refraction, Keratometry (K),topo-tomography using Sirius topo-tomography, Pachymetry, corneal haze on scale of 0 to4(0- clear cornea, 1= mild haze, 2= moderate haze, 3= severe haze, 4= reticular haze), and ectasia stability as defined by stability in mean Keratometry and Topo-tomography.

Keratoconus indices are used in diagnosis and follow up the cases post-operatively to evaluate the effectiveness of Emirates Protocol in improving the values of these indices as a guideline of visual function rehabilitation.

These Indices Are:

- 1) KVF (Keratoconus Vertex Front): The highest point of the difference between anterior corneal shape and the best-fit-asphero-toric reference- surface and measured in μm .
- 2) AKF (Apical Keratometric Front): Anterior steepest point on the Tangential anterior curvature measured in Diopter (D).
- 3) BCV (Baiocchi Calossi Versaci): The combination of RMS values of Coma, the Trefoil, and the Spherical aberration.
- 4) RMS of coma (root mean square) measured in Eq D.
- 5) RMS of the HOA measured in Eq D.

Results

All eyes showed enhancement in their vision. Coma and total HOA were enhanced. Q values are improved or maintained in a prolate form all eyes. UDVA Pre-Op mean was 20/100(0.7 logMAR), and Post-Op was 20/40(0.3 logMAR), with P Value=0.022. CDVA Pre-Op mean was 20/55(0.44 logMAR), and Post-Op was 20/30(0.17 logMAR), with P Value =0.01. Spherical equivalent (SEQ) Pre-Op mean was -5.99 D and Post-Op was -2.12 D with P Value= 0.015. K1 Pre-Op mean was 43.52 D and Post-Op was 41.31 D. K2 Pre-Op mean was 51.61 D and Post-Op was 45.79 D. Pachy Pre-Op mean was 469.63 μm and Post-Op was 339.38 μm . RMS coma Pre-Op mean was 1.79 Eq.D and Post-Op was 0.49 Eq.D with P Value= 0.006. Total HOA Pre-Op mean was 2.01 Eq D and Post-Op was 0.77 Eq.D with P Value=0.007. Q value Pre-Op mean was -0.78 and Post-Op was -0.74. AKF Pre-Op mean was 55.48 μm and Post-Op was 45.35 μm with P Value=

0.016. KVF Pre-Op mean was 36.33 μm and Post-Op was 18 μm with P Value = 0.027. BCV Pre-Op mean was 6.74 D and Post-Op was 1.46D with P Value=0.040. There was no over correction in all eyes. 3 eyes showed corneal haze more than Grade 2.All eyes showed full stability and no progression in K reading and posterior elevation map (no tomographic progression) for 12 months.

Case Reports:

Three cases were selected depending on the location of the cone with 6mm central, 6-7mm mid-peripheral, and 7-8mm peripheral.

Case1:

32 years old male with right eye progressive advanced KC and intolerant to contact lens. He was advised to do Penetrating Keratoplasty (PKP), but he refused and decided to undergo the simultaneous trans epithelial TAGCA PRK therapy of Emirates Protocol. Patient's manifest refraction was - 7.50/ -9.00 @ 3° UDVA

was 20/400(1.30 logMAR); CDVA was 20/80(0.6 logMAR), Sim-K 51.25 D @103°, Central K 41.58 D, Apical K 57.83 D @ 28° 0.20 mm from the center inferior. The thinnest corneal point was 437µm/0.80 mm infero temporal @ 210°. AKF was 57.83D/ 0.20 mm @ 281° from the center. The central corneal thickness was 454µm. KVF was 41µm/0.82 mm @198° from the center. BCV was 3.92D @198°. RMS of coma was 1.63 Eq D, and Total HOA was 2.34 Eq D. (Figure 2.A).

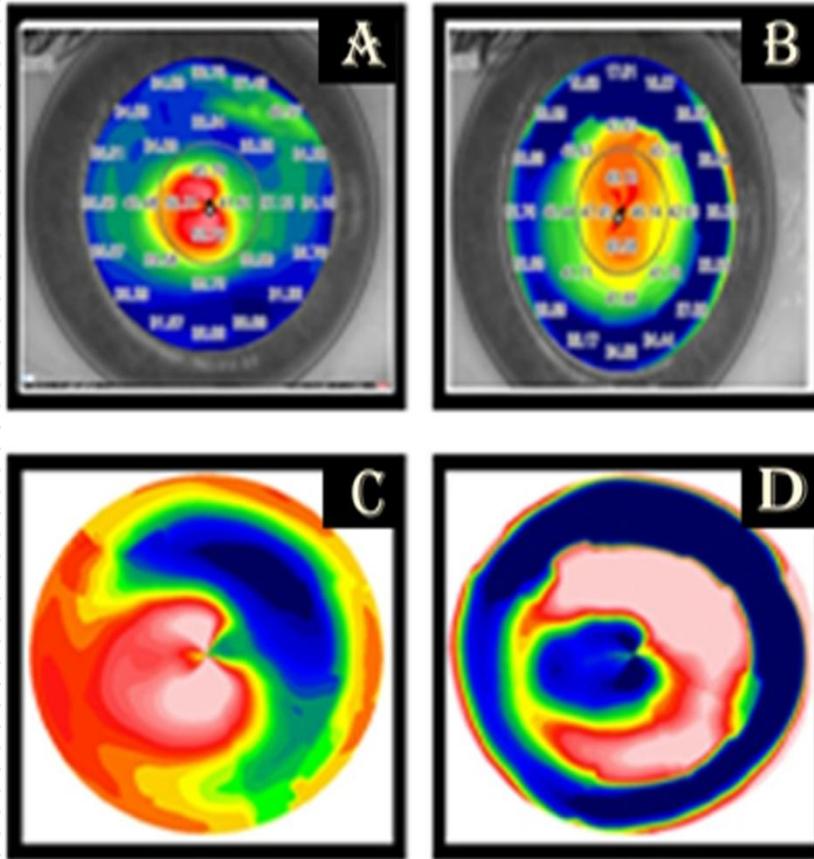


Figure 2: A) Pre-Op Sirius topo-tomography reveals infero central cone, Apical K=57.83 D. Central K =41.58 D. KVF =41µm .Refraction -7.50/-9.00 @ 3°, UDVA was 20/400; CDVA was 20/80 .Central corneal thickness= 454µm. Thinnest corneal thickness=437 µm. B) 12 months following Emirates Protocol, Sirius topo-tomography reveals greater symmetry and centrality of the steep shape, Central K increased from 41.58 D to 46.14 D. Apical K enhances from 57.83 D to 50.26 D. KVF enhances from 41 µm to 16 µm. Refraction -4.87/-0.75 @ 16°. CDVA enhanced to 20/25 .Sirius topo-tomography shows clearly the Central 7mm shows uniform symmetry, no progression in inferior steepen and uniform central steep shape. Central corneal thickness became 416 µm. C) Sirius topo-tomography Tangential difference between Pre & Post-Op shows the effect of myopic-hyperopic pattern in flattening cone's apex (coma's head), and the area opposite to the cone (tip of coma's arm) displayed in the map in red color, while the flat corneal area which is between the cone and the peripheral corneal part opposite to the cone (non treated) area displayed in blue color. D) This map shows the expected steepen of flat cornea (area between the cone& the peripheral cornea opposite to the cone) displayed in red color. C&D: Sirius shows the difference steps that lead to regularize the cornea as shown in figure B.

Patient underwent the treatment of Emirates Protocol. Upon patients manifest refraction of -7.50/ -9.0 @ 3° corneal astigmatism of -9.0 D @ 3°; corneal thinnest point of 437µm from the center, the central corneal thickness was 454µm, the outer border of cone was 2.8 mm from the geometry point; the surgeon (Dr. Al Bayati) submitted -4.00/ -6.00 @ 10° which gives a residual corneal stroma of 300µm with an optical zone of 7.00mm to cover the outer border of the cone. All information transferred with the HOA information to the Refractive modules of HOA manager. The software start analyzing all these information and gave us after 5 steps a refractive error of (-2.25/-5.50 @ 13°) comparing to refractive error that was submitted by surgeon which was (-4/-6.0 @ 10°). After completion these steps, all information will be transformed to the laser machine. Then, the remaining steps of Emirates Protocol are followed.

At 12 Months post-operatively:

UDVA enhanced from 20/400(1.3 logMAR) to 20/80(0.6 logMAR) with improvement refraction $-4.87/-0.75@16^\circ$; CDVA enhanced from 20/80(0.6 logMAR) to 20/25(0.09 logMAR). Central K increased from 41.58 D to 46.14D because of the redistribution of the K (cornea-regularization). Apical K enhanced from 57.83 D 0.20mm @281° to 50.26 D 0.20 mm @233° from the center. Sim-K enhanced from 51.25 D @103° to 48.87@92°. KVF enhances from Pre-Op 41µm to Post-Op 16µm. BCV enhance from Pre-Op 3.92 D @198° to Post-Op 1.31 D @212°. RMS of coma enhance from Pre-Op 1.60 Eq D to Post-Op 0.18 Eq D. RMS of total HOA enhances from Pre-Op 2.34 Eq D to Post-Op 0.66 Eq D. The Q value enhanced from Pre-Op -3.39 to Post-Op -1.09. The central corneal thickness Pre-Op was 454µm Post-Op became 416µm. (Figure. 2B)

Case2:

31years old male with left eye progressive advanced KC and intolerant to contact lens. He was advised to do Penetrating Keratoplasty (PKP), but he prefers to do simultaneous trans epithelial TAGCA PRK therapy of Emirates Protocol. Patient's manifest refraction was $-8.50/-4.50@220^\circ$ UDVA was 20/400(1.3 logMAR), CDVA was 20/80(0.6 logMAR). Sim-K 47.84 D @31°; Central K 39.05 D, Apical K 57.78 D/1.80mm from the center inferior @ 264°. The thinnest corneal point was 508µm/ 1.0 mm infero temporal @ 310°. AKF was 57.78 D/1.80 mm @ 261° from the center. The central corneal thickness was 524µm. KVF was 45µm/1.88 mm @ 285° from the center. BCV was 4.80D @286°. RMS of coma was 2.97Eq D, and Total HOA was 3.29 Eq D as shown in (Figure.3A).

Patient underwent the treatment of Emirates Protocol. Upon patient's manifest refraction of $-8.50/-4.50@220^\circ$, corneal astigmatism of $-4.50 D@220^\circ$; corneal thinnest point of 508µm from the center, the central corneal thickness was 528µm; the outer border of cone was 3.65mm from geometry point. The surgeon (Dr. Al Bayati) submitted $-4.50/-4.75@120^\circ$ which gave a residual corneal stroma of 300µm with an optical zone of 7.31mm to cover the outer border of cone. All information is transferred with the HOA information to

the Refractive modules of the HOA manager. The software start analyzing all these information and give us after 5 steps a refractive error of $(-3.88/-3.68@112^\circ)$ comparing to the refractive error that was submitted by the surgeon which was $-4.50/-4.75@120^\circ$; then all information is transformed to the laser machine. Then, the remaining steps of Emirates Protocol are followed.

At 12 Months post-operatively:

UDVA enhanced from Pre-Op 20/400(1.3 logMAR) to 20/60(0.47 logMAR) with improvement refraction $-3.00/-1.25@84^\circ$; CDVA enhanced from Pre-Op 20/80(0.6 logMAR) to 20/25 (0.09 logMAR). Central K increased from Pre-Op 39.05 D to 42.30 D because of the redistribution of the K (cornea -regularization). Apical K enhanced from Pre-Op 57.78 D 1.80 mm @264° to 53.49 D 3.40 mm @274° from the center. Sim-K enhanced from Pre-Op 47.84 D @31° to 42.68 @27°. KVF

enhanced from Pre-Op 45 μ m to 20 μ m. BCV enhances from Pre-Op 4.80D @286° to 2.92D @ 284°. RMS of coma enhanced from Pre-Op 2.97Eq D to 1.34 Eq D. RMS total HOA enhances from Pre-Op 3.29 Eq D to 1.64 Eq D. The Q value changed from Pre-Op 0.07 to -0.94. The central corneal thickness Pre-Op was 528 μ m Post-Op became 309 μ m as shown in (Figure3.B).

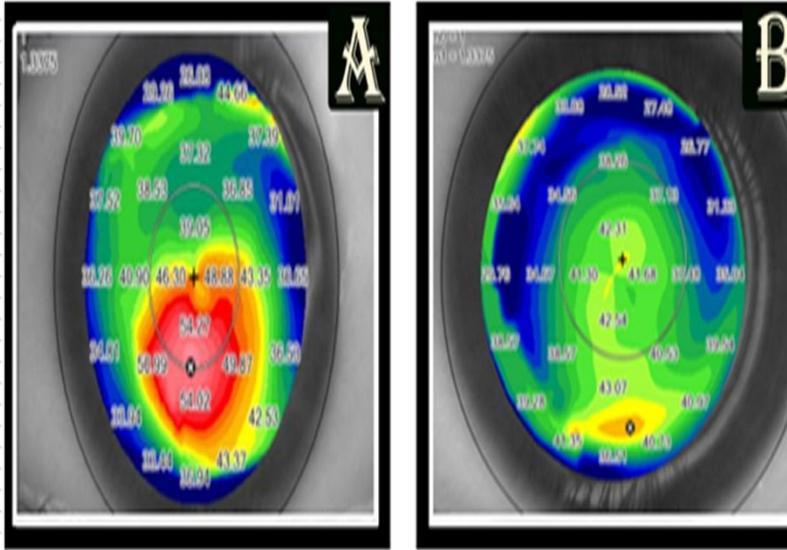


Figure 3: A) Pre-Op Sirius topo-tomography reveals infero central cone, Apical K= 57.78 D. Central K =39.05 D. KVF =45 μ m. Refraction -8.50/-4.50@220°; UDVA was 20/400; CDVA was 20/80 .The central corneal thickness= 528 μ m, the thinnest corneal thickness=508 μ m. B) 12 months following Emirates Protocol, UDVA enhanced to 20/60 .Refraction -3.00/-1.25@84°; CDVA enhanced to 20/25. Central K increased from Pre-Op 39.05 D to 42.30 D due to redistribution of the K cornea's regularization. Apical K enhanced to 53.49 D. Sim-K enhanced to 42.68 D. KVF enhanced from Pre-Op 45 μ m to 20 μ m. The central corneal thickness became 309 μ m. Sirius topo-tomography shows clearly the Central 7mm shows uniform symmetry, no progression in inferior steepen ,and uniform central steep shape .

Case3:

31years old male with right eye progressive advanced KC and intolerant to contact lens. He was advised to do intra corneal ring but he refused and decided to undergo the simultaneous trans epithelial TAGCA PRK therapy of Emirates Protocol. Patient's manifest refraction was -5.75/ -5.25@ 80°. UDVA was 20/200(1.0 logMAR), CDVA was 20/50(0.4 logMAR). Sim-K 45.40 D @ 163°. Central K 44.35 D, Apical K 55.12 D/3.00mm from the center inferior @ 300°. The thinnest corneal point was 532 μ m/ 1.20 mm infero temporal @ 240°.

AKF was 55.12 D/3.00mm from the center inferior @ 300°. The central corneal thickness was 544 μ m. KVF was 51.35 μ m/2.40 mm @ 285° from the center. BCV was 1.73 D @263°. RMS of coma was 1.35 Eq D, and Total HOA was 1.62 Eq.D (Figure.4A). Patient underwent the treatment of Emirates Protocol. Upon patient's manifest refraction of was -5.75/ -5.25@ 80°; corneal astigmatism of - 5.25 D@80°, corneal thinnest point of 532 μ m from the center ,the central corneal thickness was 544 μ m, the outer border of the cone was 3.98mm from the geometry point. The surgeon (Dr. Al Bayati) submitted -3.50/-3.75@78° which gave a residual corneal stroma of 300 μ m with an optical zone of 7.97mm to cover the outer border of cone. All information is transferred with HOA information to the Refractive modules of the HOA manager. The software start analyzing all these information and gave us after 5 steps a refractive error of (-2.89/-2.73@70°) comparing to the refractive

error that was submitted by the surgeon which was $-3.50/-3.75 @78^\circ$. All the information is transformed to the laser machine, then it followed by the remaining steps of Emirates Protocol.

At 12 Months post-operatively:

UDVA enhanced from Pre-Op 20/200 (1.0 logMAR) to 20/40(0.3 logMAR) with improvement refraction $-1.25/-3.50@98^\circ$, CDVA enhanced from Pre-Op 20/50(0.4 logMAR) to 20/25(0.09 logMAR). Central K enhanced from Pre-Op 44.35 D to 41.22 D. Apical K enhanced from Pre-Op 55.12D 3.00 mm@ 300° to 41.16 D 3.00 mm @ 300° from the center. Sim-K enhanced from Pre-Op 47.84D @ 31° to 42.68@ 27° . KVF enhanced from Pre-Op 51.35 μ m to 18 μ m BCV enhances from Pre-Op 1.73D @ 263° to 0.52D @ 151° . RMS coma enhances from Pre-Op 2.97 Eq D to 1.34 Eq D . RMS of Total HOA enhance from Pre-Op 3.29 Eq D to 1.64 Eq D. The Q value enhanced from 1.09 to 0.50.The central corneal thickness Pre-Op was 544 μ m Post-Op became 342 μ m as shown in (Figure.4B).

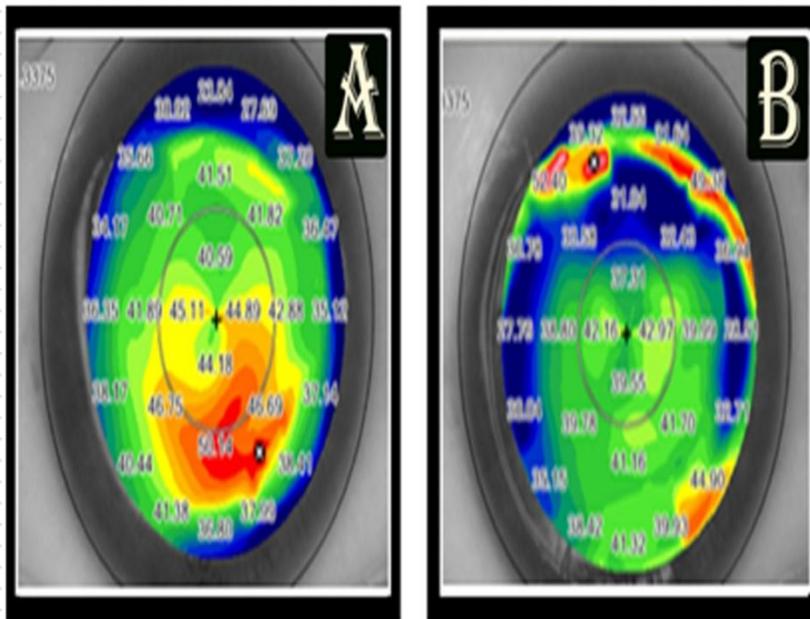


Figure 4: A) Pre-Op Sirius topo-tomography reveals infero central cone, Apical K=55.12D. Central K =44.35 D. KVF =51.35 μ m .Patient’s refraction $-5.75/-5.25 @ 80^\circ$; UDVA was 20/200; CDVA was 20/50.The central corneal thickness=544 μ m, the thinnest corneal thickness=532 μ m.
 B) 12 months following simultaneous Emirates Protocol, UDVA enhanced to 20/40 with refraction $-1.25/-3.50@98^\circ$, CDVA enhanced to 20/25. Central K enhanced to 41.22 D. Apical K enhanced to 41.16 D from the center. Sim-K enhanced to 42.68 D.KVF enhanced from Pre-Op 51.35 μ m to 18 μ m.The central corneal thickness became 342 μ m. Sirius

Discussion

Regularizing the corneal irregularity with simultaneous combination of TAGCA PRK / ACXL and its synergetic action (regularizing and stabilizing the cornea) is one of important events in KC treatment. ¹²⁻¹⁸

In our opinion, Cornea’s Regularization needs:

- 1-Detection of corneal HOA & the ability to select the most clinically significant types, and treat them through a highly selective profile.
 - 2- Ability to incorporate the selected HOA with refractive error algorithmically to prevent any over correction.
 - 3-The optical zone of the TAGCA PRK should cover the outer border of cone in relation to the geometrical center of the cornea.
- If the optical zone doesn’t cover the outer border; the regularization process of the cornea will not be achieved because the principle of this process depends on:

-Myopic-hyperopic pattern ablation that is unique to the KC, because it simply represents the coma which forms 90% of the corneal HOA (myopic part represented by head of coma, while hyperopic part represented by the tip of coma's arm which is opposite of the cone).

The myopic part flattens the cone's apexes while the hyperopic part flattens the corneal periphery, which is usually superior nasal. Flattening the cone's head and the cornea's periphery opposite to the head leads to steepen the corneal center, which is in between. (Figure5).

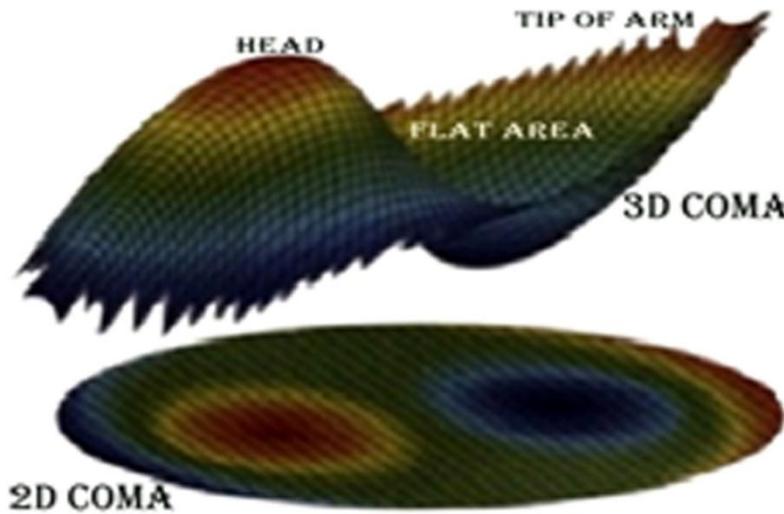


Figure 5: 3 dimensions & 2 dimensions of coma shows 3 different areas: the Head of the coma, the Tip of its arm which is opposite to the head and resembles the steep area, and the third is the Flat area which is between the Head and the Tip of the arm.

This performance will lead to corneal regularization by recentering the flattened (treated) cone.

The whole cone should be treated in order to regularize the cornea; otherwise treating part of cone (the central part) will not lead to steepen the flat corneal area (between the cone and the peripheral part of the cornea). Keeping the cone's peripheral part untreated with TAGCA PRK leads to progression at this part especially when it is not treated with ACXL, and it also leads to steepen it because of the flattening effect of the cone's central part by laser. This explains why in Athens protocol they have good results when the cone is within their optical zone and they have less effective results when the cone outer border is outside their optical zone.

(Progression of the outer border of cone increases the existent myopia).¹²⁻¹⁸

-HOA area that will read by the corneal map should cover the outer border of cone. Neither less nor more, otherwise will we end up with unpredictable results.

-HOA area of 8mm cannot be applied on optical zone of 5.5 mm. Sirius corneal map has the ability to read the corneal HOA in different zones 3,5,6,7... so we can follow the cone's outer border precisely and with more predictable information.

- In highly irregular corneas (KC), the refractive ablation without the use of corneal HOA is not effective in regularizing the corneal's surface because it can't treat the coma which forms the main corneal HOA in KC.

-Treating the coma from the main corneal HOA in KC is the core concept in TAGCA PRK treatment (coma is responsible for myopic-hyperopic ablation pattern).

Why Not Ocular Wavefront?

Ocular Wavefront analysis has some limitations in analyzing and correcting irregular cornea because:

- Most sensors can't measure highly aberrated corneas¹⁹.
- Ocular Wavefront analysis is restricted by pupil size and affected by patient's accommodation¹⁹.
- Most Ocular Wavefront sensors limit the analysis to 1mm inside the pupil diameter, which limits the knowledge of the corneal irregularity¹⁹.

Why Corneal Wavefront?

- Corneal Wavefront is a mathematical analysis of corneal topography (elevation map) by measuring the abnormality of anterior corneal surface, incorporating it in the Zernike polynomial 7th orders¹⁹.
- Corneal Wavefront analysis can measure up to 8.5 mm of corneal diameter¹⁹.
- Corneal Wavefront is not limited to pupil size, but measures much larger amount of points, which renders much more accurate information on the corneal irregularity and it is not affected by patient's accommodation¹⁹.
- IV. Corneal Wavefront analysis can be obtained almost in any case of corneal irregularity even in highly aberrated cornea¹⁹.

4-The continuous trans epithelial ablation of Schwind AMARIS with the refractive ablation is aspheric (55µm for the center and 65µm for the periphery) enables us to reach upto 8mm without leaving any remnant of epithelial tissues specially in the periphery part of the cornea, and enables us to smoothen the cornea's surface by removing part of the cone's apex where the epithelial layer is thin 30µm -35µm (remodeling effect).Through this process the refractive ablation that follows the trans epithelial ablation will be applied on smoother surface that matches the corneal's maps details properly. On the other hand, in manual epithelium

removal; the corneal surface will not match the corneal's map pictures because of the epithelial remodeling effects.

5- Schwind's AMARIS customized ablation which compensates for the induced spherical aberration able us to reach up to 8 mm optical zone without oblatting the cornea (maintain and treat the Q value). Reaching the outer border of cone without oblatting the cornea gives us the ability to treat most of cones depending on their location: (central cone outer-border within 5 -6 mm, mid-peripheral cone within 6-7 mm and peripheral cone between 7-8 mm).

The rule of CXL in stabilizing post Lasik ectatic corneas as has been published shows the thickness of the corneal's bed is less than 300 µm, and as the corneal's strength totally depends on the corneal bed only ,and no rule of the corneal's flap. All these studies showed a very good stability after CXL. By relying on these facts; we found out that by keeping the central corneal thickness and the thinnest corneal part not less than 300 µm is good enough biomechanically with use of ACXL to stabilize the cornea and to prevent any progression in the previous cone's bed.

6- Advanced tracking system with 6 dimensions. (Figure.6)

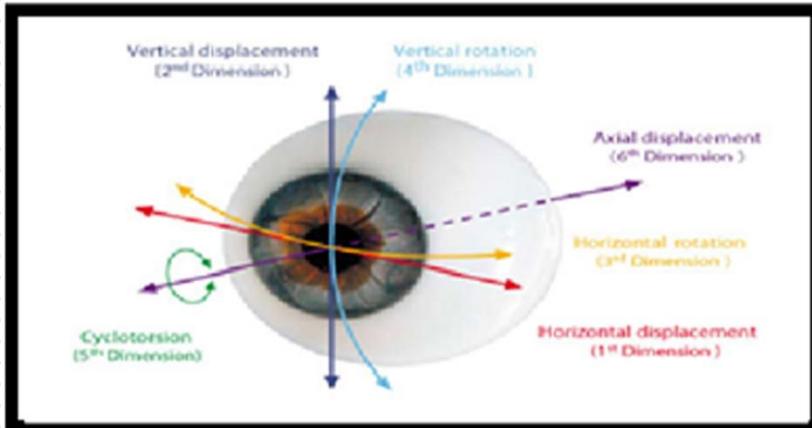


Figure 6: 6D tracking system of Schwind AMARIS Laser Machine.

-This system is able to treat myopic-hyperopic pattern in precise and accurate way. (Figure.7)

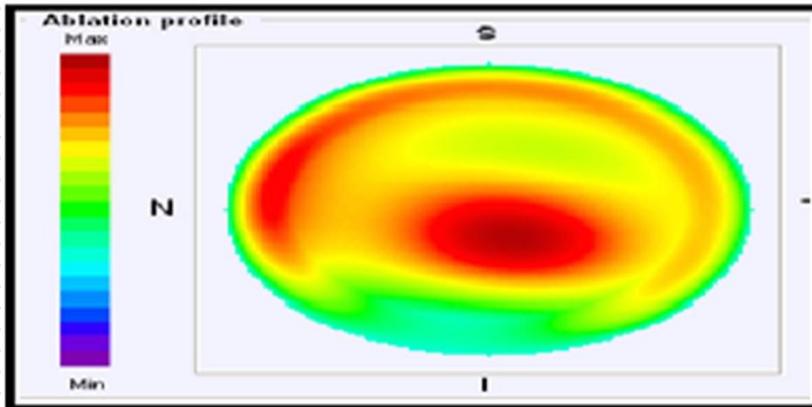


Figure 7: Schwind's AMARIS laser machine Ablation profile in which the myopic-hyperopic pattern is shown clearly. This pattern needs highly advanced (6D tracking system) static & dynamic to be able to track the ablation pattern.

The new corneal shape after TAGCA PRK (less irregular, smoother, and prolate corneal shape) performs better biomechanically in eyes with corneal ectasia especially as the corneal apex becomes flatter and broader cone. This may redistribute the mechanical strain from the eyes intraocular pressure and other external factors (e.g. eye rubbing, blinking, etc). This effect may be further enhanced with an additional ACXL strengthening.

Simultaneous TAGCA TPRK with ACXL is much better than sequential form because of the following: ²⁰⁻²³

A-One procedure instead of two, to reduce time off work

B-There is no need to remove cross-linked cornea.

C- Less PRK associated scarring: CXL eliminates the keratocyte that will transform into Fibroblast, which is the source of collagen that creates fibrosis in the separate form.

D-More effective cross-linking: Removing Bowman Membrane may facilitate Riboflavin solution penetration in the corneal stroma, and less UVA light shielding through the cornea for more effective cross-linking

By using TAGCA PRK trans epithelial we do not have any over corrections nor any increase in the existing myopia because of:

1-The use of Refractive module in the management of HOA, which incorporates the highly selected HOA with the refractive error of the in algorithmic way not in algebraic summation.

2-Regularize the cornea precisely despite of the cone's location, because the optical zone covers the outer border of cone.

Most of over correction and increase in existing myopia occurs when the optical zone doesn't cover the outer border of the cone, which means it covers the central part of the cone only.

Simultaneous TAGCA-PRK and ACXL appears to be effective in the rehabilitation of KC. The reality of efficacy of this treatment is shown clearly through reduction of the penetrating Keratoplasty cases PKP in our practice in the last 2 years. Our findings in those 30 eyes suggest highly promising results with simultaneous TAGCA-PRK and ACXL as a therapeutic intervention in highly irregular corneas with progressive corneal ectasia, especially in Emirates protocol we can overcome most of the difficulties that has been occurred in Athens protocol (over correction, increase in existing myopia and progressing outer border of the cone).¹²⁻¹⁸

Emirates Protocol shows a new mean in its ability of improving the visual quality, correcting the refractive error of KC, adding to the original means in avoiding or delaying penetrating Keratoplasty.

WHAT WAS KNOWN

Regularizing the corneal irregularity with simultaneous combination of TGCA PRK and CXL by using using T-CAT module of Allegretto Wave Eye-Q Excimer laser (Alcon Laboratories Inc) and its synergetic action (regularizing and stabilizing the cornea) is one of important events in KC treatment that's created by Prof. Kanellopoulos .

WHAT THIS PAPER ADDS

-New laser concept using same synergetic action of laser and Accelerated Cross- Linking (ACXL) both at one session but using topographic aberrometric guided customized ablation trans epithelial PRK laser TAGCA PRK by Schwind AMARIS 750s.

-The treatment profile of this laser is guided by corneal wave front Corneal High Order Aberration (H.O.A) which is derived from the corneal elevation map incorporated into Zernike Polynomials.

-The optical zone of the TAGCA PRK covers the outer-border of the cone

-Corneal HOA is important in diagnosis, treatment, and follow up in KC.

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