Egyptian Consensus on Keratoconus Management: an EPK-Group Research Project

Protocol study

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INTRODUCTION

Keratoconus is an ectatic disease of the cornea characterized by localized progressive thinning and forward protrusion of the cornea.[1] There have been several management options discussed for keratoconus including collagen crosslinking (CXL), topography guided ablation, intrastromal corneal ring segment (ICRS) implantation and keratoplasty.[2-7]

ICRS have been found to be useful in correcting ectatic corneal disorders by reducing corneal steepening and decreasing irregular astigmatism thus potentially improving the visual acuity. It can also be considered as an option to defer if not eliminate, the need for keratoplasty in these patients.[1-7]

Improvement in visual acuity and refraction after ICRS implantation is accomplished by a shortening of collagen lamellae along the arc length of the ring. There is a redistribution of corneal stress due to the change in the shape of the cornea after implantation of ICRS.[8,9]

Myoring is a 360° continous full-ring implant to be implanted into a corneal pocket for the treatment of Myopia and Keratoconus. The internationally patented device combines two a-priori contradictory qualities: rigidity for the modelling and stabilisation of the corneal shape after implantation and flexibility (shape memory) for the implantation via a small pocket entry to preserve the corneal biomechanics. The nomogram for the selection of the right Myoring dimension for keratoconus is very simple and depends only on the value of the central K average-reading according to (SIM K1 + SIM K2)/2.[9]

Keraring (Mediphacos Inc., Belo Horizonte, Brazil) is an ICRS that is used to treat keratoconus. It acts by regularizing the anterior corneal surface, thus decreasing the myopia and regular and irregular astigmatism. They are available in different arc lengths and are made of polymethylmethacrylate (PMMA). They are triangular in cross section in contrast to other ICRS such as Ferrara rings and they have a 600 μm base and an apical diameter of 5 mm. [10]

Femtosecond laser technology allows a surgeon to program a corneal stromal dissection at a predetermined depth with an extremely high degree of accuracy, thus avoiding the potential inaccuracies of a mechanical dissection that is dependent on the surgeon's manual skills.[11]

Corneal Collagen Cross-Linking strengthens the stromal collagen fibrillae of the cornea halting and stabilizing the evolution of keratoconus with a long-term increase in corneal biomechanical rigidity. CXL stiffens the human cornea by approximately 300%, increases the collagen fiber diameter by 12.2%, and induces the formation of high molecular-weight collagen polymers, with a remarkable chemical stability.[12]

Many protocols had been developed previously for treatment of keratoconus or a particular stage of keratoconus as Athens protocol. The findings suggest potentially promising results with same-day, simultaneous topography-guided PRK and collagen CXL (Athens Protocol) as a therapeutic intervention in highly irregular corneas with keratoconus and progressive post-LASIK ectasia. We have reported for the first time effective CXL treatment in cases with minimal thickness (< 350 μm). It is unfortunate that topography-guided ablations are not yet available in the United States. [13]

PURPOSE

To analyse the pre and postoperative results of 500 keratoconic eyes that had underwent one or more surgical procedures weather combined or consecutively in Egypt to construct a specialized professional protocol for management of all stages of keratoconus. This protocol is to be named the Egyptian Protocol for Keratoconus Management (EPK) which will be specially prepared for the treatment of the Egyptians keratoconic patients.

PATIENTS AND METHODS

Design: A Prospective clinical study.

The authors will obtain the approval of the Institutional Research Board in Faculty of Medicine Sohag University.

This study will include 750 eyes with keratoconus that no previous surgical interference with or without additional refractive visual aids (e.g. glasses, contact lenses, RGP or other corneal or scleral hard contact lenses). There will be one control group (250 KC patients) and 4 experimental groups. ICRS group (150 KC patients) and will be subjected to Kera rings implantation with femtosecond laser. ACXL group (150 KC patients) and will be subjected to Accelerated epithelium-off CXL, 9 minutes soaking time with riboflavin, 9 minutes UVA corneal irradiation pulsed mode. SCXL group (100 KC patients) and will be subjected to Conventional epithelium-off CXL, 14 minutes soaking time with riboflavin, 30 minutes UVA corneal irradiation continuous mode. CXLPLUS group (100 KC patients) and will be subjected to Kera rings implantation with femtosecond laser to be followed

immediately by accelerated CXL, 10 minutes soaking time with riboflavin, 8 minutes UVA corneal irradiation pulsed mode.

Preoperative and postoperative evaluation will include complete ophthalmologic examinations that included measurement of the uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA) and slit lamp examination of anterior segment with keratometry and pachymetry assessed by Pentacams. All stages of keratoconus and all management plans will be included in this study. All eyes included in this study must have at least 1 year follow up. No exclusion criteria in this study as EPK aims at determining the decision making in all stages of keratoconus whatever the condition of the eye is.

REFERENCES

1- Torquetti L, Berbel RF, Ferrara P. Long-term follow-up of intrastromal corneal ring segments in keratoconus. J Cataract Refract Surg. 2009;35:1768–73.

2- Ertan A, Kamburoğlu G. Intacs implantation using a femtosecond laser for management of keratoconus: Comparison of 306 cases in different stages. J Cataract Refract Surg. 2008;34:1521–6.

3- Barraquer JI. Modification of refraction by means of intracorneal inclusions. Int Ophthalmol Clin. 1966;6:53–78.

4- McDonald MB, Kaufman HE, Durrie DS, Keates RH, Sanders DR. Epikeratophakia for keratoconus. The nationwide study. Arch Ophthalmol. 1986;104:1294–300.

5- Buratto L, Belloni S, Valeri R. Excimer laser lamellar keratoplasty of augmented thickness for keratoconus. J Refract Surg. 1998;14:517–25.

6- Koch DD. Refractive surgery for keratoconus: A new approach. J Cataract Refract Surg. 2000;26:1099–100.

7- Sekundo W, Stevens JD. Surgical treatment of keratoconus at the turn of the 20th century. J Refract Surg. 2001;17:69–73.

8- Burris TE, Ayer CT, Evensen DA, Davenport JM. Effects of intrastromal corneal ring size and thickness on corneal flattening in human eyes. Refract Corneal Surg. 1991;7:46–50.

9- DIOPTEX, CISIS, POCKETMAKER and MYORING. Available at http://www.dioptex.com/products/myoring-corneal-implant. Accessed at April 15, 2014

10- MEDIPHACOS Ophthalmic Professionals. Available at http://www.mediphacos.com/en/produtos_implanteIntraEstromalKeraring.asp. Accessed at April 9, 2014

11- Coskunseven E, Kymionis G, Tsiklis N, et al. One-year results of intrastromal corneal ring segment implantation (KeraRing) using femtosecond laser in patients with keratoconus. Am J Ophthalmol. 2008; 5:775-9.

12- Spoerl E, Hafezi F, Bradley J. Corneal Collages Cross-Linking. SLACK Incorporated 2013;20:139-42.

13- KANELLOPOULOS J. The Athens Protocol-The management of keratoconus and post-LASIK ectasia by means of combined, same-day, topography-guided partial PRK and collagen cross-linking. CATARACT & REFRACTIVE SURGERY TODAY AUGUST 2011. P: 31-4