Evaluation of a New Technique to Increase The Corneal Cross-linking Efficacy by Raising The Corneal Temperature During Ultra-Violet Light A Corneal Irradiation (Hot Cross-linking) for Kearatoconus Treatment

PROTOCOL STUDY

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INTRODUCTION

Keratoconus is a progressive non-inflammatory corneal disorder which is characterized by irregular apical conical protrusion with corneal stromal thinning characterized by progressive diminution of vision due to myopia and astigmatic components of KC. Many parameters were used to define the progression of KC mainly the anterior and posterior K readings, central corneal thickness at the thinnest location and the back surface elevations. The continuation of the progression of at least 2 of the previous parameters indicates the progression of KC.¹⁻³

Amsler-Krumeich classification is one of the most famous classifications of KC. It graded KC into 4 grades depending on the mean K readings, myopic and astigmatic component of KC and corneal thickness. Grade 1 included mean central K readings < 48 diopters with myopia, induced astigmatism, or both <5.00 D and corneal thickness >400 μ m. Grade 2 included mean central K readings ≥ 48 - < 54 diopters with myopia, induced astigmatism, or both from 5.00 to 8.00 D and corneal thickness >400 μ m. Grade 3 included mean central K readings ≥ 54 - < 55 diopters with myopia, induced astigmatism, or both from 5.00 to 8.00 D and corneal thickness astigmatism, or both from 8.00 to 10.00 D and corneal thickness 300 - 400 μ m. Grade 4 included mean central K readings ≥ 55 diopters with immeasurable refraction.⁴

Nowadays, it has been settled that corneal collagen cross-linking (CXL) is the only true therapeutic treatment for KC due to its ability to halt the pathological progression of the disease. Furthermore, many authors reported the advantage of epithelium-off CXL in flattening of the keratoconic cornea

thus reducing the myopic component of KC and helping in correcting the refractive status of KC hence the idea of both therapeutic and refractive CXL.^{5,6}

Corneal collagen cross-linking (CXL) is the actual and main treatment to keratoconus and has the advantage of halting the progression of the pathology of the disease. The progression of keratoconus can be defined by continues change in 2 or more of special parameters. These special parameters included steepening of the posterior K readings, steepening of the anterior K readings, thinning of the centeral pachymetry readings and high back surface elevations. 5 Cross-liking PLUS (CXL PLUS) is defined as the simultaneous combination of CXL and a refractive procedure to flatten the cornea and improve vision as ICRS implantation.^{6,8}

In healthy volunteers, the cornea required at least 20–30 min to adapt to change in ambient temperature. The relationship between corneal and external temperature was relatively linear. At the two extremes, +83°C and _40°C, the corneal temperature was +42°C and +25.1°C, respectively. In the experimental setting, corneal temperature was +24.3°C at air temperature _40°C. A rather stable aqueous humour temperature of +37°C and high thermal conductivity of the corneal tissue prevent corneal frostbite even at extremely low ambient temperatures.^{9,10}

PURPOSE

To evaluate efficacy of corneal cross-linking when the corneal temperature is raised to 37-39°C during UVA corneal irradiation for treatment of KC.

DESIGN

A prospective randomized controlled clinical trial

PATIENTS AND METHODS

The author will obtain the approval of the ethical committee in Faculty of Medicine in Sohag University Hospital and informed consent will obtain from all patients. This study will be conducted on 50 eyes who had grade 1,2 and 3 KC. All 50 eyes will be devided into four groups. Group A (SCXL Group) will include 20 eyes to be subjected to standard CXL. Group B (37°C HCXL Group) will include 10 eyes of volunteers to be subjected to SCXL after ensuring that the corneal temperature has reached 37°C. Group C (38°C HCXL Group) will include 10 eyes of volunteers to be subjected to SCXL after ensuring that the corneal temperature has reached 37°C. Group D (39°C HCXL Group) will include 10 eyes of volunteers to be subjected to SCXL after ensuring that the corneal temperature has reached 39°C. Group D (39°C HCXL Group) will include 10 eyes of volunteers to be subjected to SCXL after ensuring that the corneal temperature has reached 39°C. Preoperative and intraoperative corneal temperature will be measured using a non-contact infrared thermometer.

All eyes will be subjected to preoperative and postoperative Pentacams included pachymetry, keratometry, subjective refraction and uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA).

Comparisons will be made between the preoperative patients' data before the first CXL session and the patients' data that will be collected in the present time.

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