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Theoretical model and design of a device to reduce the influence of environmental factors on refractive surgery outcomes.

Emiliano Schena, Sergio Silvestri, Giovanni Talei Franzesi, Gaetano Cupo, Pino Carito, Emiliano Ghinelli

Abstract—**Recently many different groups show that environmental temperature and relative humidity affect the outcomes of refractive surgery performed by excimer lasers in an unpredictable fashion. A theoretical model of the water vapor absorption at 193 nm wavelength is presented and discussed in order to quantitatively assess the influence of environmental parameters on the laser energy that actually reaches the corneal surface. Model simulations show that laser energy absorption (up to 7% of the available energy) occurs along the path of laser beam, into the existent space between the laser beam source and the patient's eye, and is caused by environmental temperature and relative humidity (respectively 35°C and 95%). Our findings suggest that this energy loss reduces the ablation rate, producing a significant under-correction of the treated corneas. A cost effective device which keeps thermo hygrometric parameters constant along the laser beam path, is also provided.**

I. INTRODUCTION

EXPERIMENTAL observations showed that environmental factors, such as temperature and relative humidity, can affect the outcomes of laser in situ keratomileusis refractive surgery (LASIK) [1].

The LASIK procedure (but also PRK etc.) consists in an excimer 193 nm wavelength laser, to photo ablate the corneal stroma in order to generate a refractive change modifying the corneal shape. The aim of refractive procedures (RP) is to achieve emmetropia at once. However, sometimes further interventions may be needed to obtain optimal correction [2].

A relatively high number of under-corrected RP has been observed in association with humid and warm environments, whereas a high number of over-corrected RP has been observed in dry and colder ones [1]. These events are related to the hydration of the cornea which determines its thickness, thus the depth of ablation might be deeper in less hydrated corneas and more superficial in more hydrated ones [1], [2]. Environmental variables, which are surgeon-independent, appear to influence the procedure outcomes in an unpredictable way. For this important reason it has been recently suggested to update the normograms tables currently used by refractive surgeons considering room temperature and relative humidity [2], [3].

To investigate the influence of thermo hygrometric levels on RP, we hypothesized that, the hydration level of the cornea and the laser energy absorption from the source to the eye, may affect the final energy amount that reaches the cornea. Assuming that the more humid the environment the higher the concentration of water molecules are present along the path of the laser source-eye, and considering that the less the energy density reaches the cornea the smaller quantity of tissue is ablated, we identified a mathematical model (based on these factors/to correct or adjust for these factors).

The model points out the water absorption at 193 nm wavelengths, the relative humidity of the room and how significantly the ablation rate diminishes in terms of microns per laser pulse. We describe a simple device designed to keep temperature and relative humidity of the air surrounding the excimer laser beam during RP under control.

II. THEORETICAL MODEL AND SIMULATION

The proposed model includes: the energy absorption, due to water vapor, the ablation rate and the environmental thermohygrometric parameters.

Current medical literature indicates that energy density per pulse is commonly indicated as 'fluence'.

The laser fluence which effectively reaches the cornea (I_c), can be expressed as a function of the fluence at the source of the laser (I_0), using the Beer-Lambert equation:

$$I_c = I_0 \exp(-ckz) \qquad (1)$$

where I_0 is the fluence of laser radiation [mJ·cm^{-2}], c is the concentration of the environment water vapor [molecules·cm^{-3}], k is the absorption coefficient of water vapor [cm^2·molecules^{-1}] and z is the radiation trip length [cm], which is the laser arm-eye distance (in our case 25 cm).

Equation (1) allows calculating the ratio between the fluence that reaches the cornea (I_c) and fluence at the laser source (I_0) as a function of the absorption parameters. The absorption coefficient of water-vapor k varies with temperature and relative humidity. However, according to literature [4], this parameter has been considered constant at 193 nm wavelengths, and between 15 and 35°C is equals to

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E. Schena and S. Silvestri are with the Faculty of Biomedical Engineering, University Campus Bio-Medico of Rome, Italy (corresponding author S. Silvestri phone: +39-06-225411; fax: +39-06-22541751; e-mail: s.silvestri@ unicampus.it).

G. Talei Franzesi is with the Massachusetts Institute of Tecnology, Cambridge, USA.

P. Carito and E. Ghinelli are with the Laboratorio di Biotecnologie e Scienze della Visione, Casa di Cura Dott. Pederzoli, Peschiera del Garda, Verona.

G. Cupo is with the Fondazione Bietti per L'Oftalmologia, Roma.

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$2 \cdot 10^{-21}$ cm^2· molecules^{-1}.

The concentration of water molecules c can be easily calculated by the definition of relative humidity. In Table I values of water vapor concentration are expressed as a function of relative humidity (RH) at 15°C, 20°C and 35°C.

TABLE I
CONCENTRATION OF WATER-VAPOR AT 15°C, 20°C AND 35°C
(FUNCTION OF RELATIVE HUMIDITY)

RH [%]	Concentration @15°C $\left[\frac{molecules}{cm^3}\right]$	Concentration @20°C $\left[\frac{molecules}{cm^3}\right]$	Concentration @35°C $\left[\frac{molecules}{cm^3}\right]$
10	$0.42 \bullet 10^{17}$	$0.59 \bullet 10^{17}$	$1.47 \bullet 10^{17}$
20	$0.85 \bullet 10^{17}$	$1.18 \bullet 10^{17}$	$2.94 \bullet 10^{17}$
30	$1.28 \bullet 10^{17}$	$1.77 \bullet 10^{17}$	$4.40 \bullet 10^{17}$
40	$1.70 \bullet 10^{17}$	$2.36 \bullet 10^{17}$	$5.87 \bullet 10^{17}$
50	$2.13 \bullet 10^{17}$	$2.95 \bullet 10^{17}$	$7.34 \bullet 10^{17}$
60	$2.55 \bullet 10^{17}$	$3.54 \bullet 10^{17}$	$8.81 \bullet 10^{17}$
70	$2.98 \bullet 10^{17}$	$4.13 \bullet 10^{17}$	$1.03 \bullet 10^{18}$
80	$3.40 \bullet 10^{17}$	$4.72 \bullet 10^{17}$	$1.17 \bullet 10^{18}$
90	$3.83 \bullet 10^{17}$	$5.31 \bullet 10^{17}$	$1.32 \bullet 10^{18}$
100	$4.25 \bullet 10^{17}$	$5.50 \bullet 10^{17}$	$1.47 \bullet 10^{18}$

Finally, in order to calculate the percentage of the fluence lost along the path we assumed for I_0 the typical values used during corneal ablation: from 100 mJ·cm^{-2} up to 250 mJ·cm^{-2}. Fig.1 represents a graphical expression of the I_C/I_0 ratio, using equation (1) with the c values reported in table I.

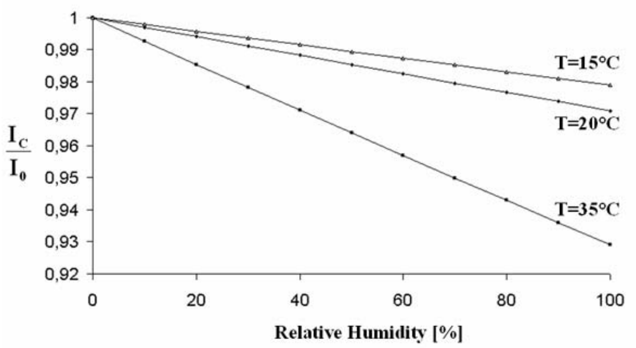

Fig. 1. Ratio between the fluence on the cornea I_c and the fluence at laser exit I_0 as a function of the relative humidity and the temperature

In order to estimate how the energy absorption (EA) affects the ablation rate we must consider that EA levels are a logarithmic function of the fluence. The fluences of commercially available medical excimer lasers ranges from 100 mJ·cm^{-2} up to 250 mJ·cm^{-2} which corresponds to ablation rates from 0.2 μm/pulse to 0.7 μm/pulse [5]. By logarithmic regression of the data reported in literature [6], [7] we obtained the following relation:

$$Y = A \log(I) - B \qquad (2)$$

where Y is the ablation rate [μm/pulse], I is the fluence, A and B equals to 1 μm/pulse and 1.98 μm/pulse respectively.

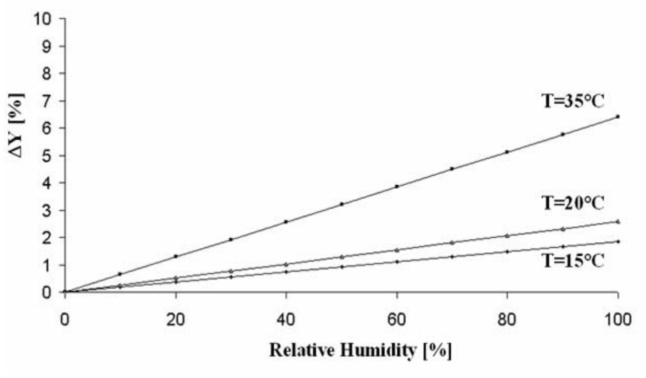

Fig. 2. ΔY as a function of the thermohygrometric parameters (I_0=250 mJ·cm^{-2})

From (2) the ablation rate percent variation ΔY expressed as a function of the thermohygrometric parameters can be calculated as follows:

$$\Delta Y = \frac{Y_0 - Y_C}{Y_0} \cdot 100 \qquad (3)$$

where Y_0 is the ablation rate obtained substituting I_0 in (2) and Y_C the working ablation rate (calculated from the fluence absorption along the path), obtained substituting I_C in (2).

Due to the logarithmic relationships of (2) the ΔY values are a non-linear function of the fluence and for this reason a higher percent of energy loss is present at low energies. Figure 2 shows ΔY as a function of the thermohygrometric parameters where I_0 equals 250 mJ·cm^{-2}.

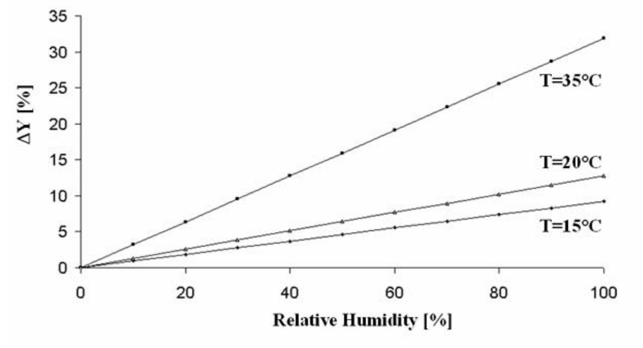

Fig. 3. ΔY as a function of the thermohygrometric parameters when I_0=100 mJ·cm^{-2}.

The maximum ΔY is equal to 7% and it is observed at 35°C and 95% RH.

In smaller fluence value conditions (I_0 = 100 mJ·cm^{-2}) the maximum ΔY observed equals 32% and it is obtained at 35°C and 95% RH as reported in figure 3.

As showed in figure 3, the ablation rate appears to be strongly influenced by thermo hygrometric parameters as the fluence lost is higher at lower energies.

III. PRELIMINARY EXPERIMENTS

In order to validate the above described theoretical model, some preliminary experiments have been carried out with an excimer laser (ESIRIS – Schwind) at two values of environmental temperature (21±1°C and 25±1°C) and several values of relative humidity from 35 to 55%. Laser fluence has been set to 180 $mJ \cdot cm^{-2}$ and the ablation rate has been measured on a target furnished with the laser set to run fluence test before any RP.

Results reported in figure 4 show a general diminution of the ablation rate for increasing values of relative humidity. Moreover, at same values of relative humidity there is a decrease of the ablation rate for increasing values of the temperature.

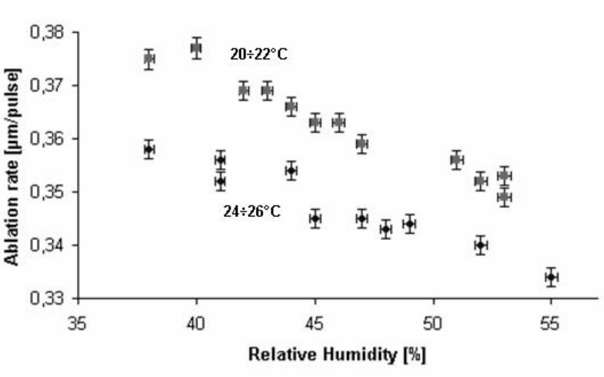

Fig. 4. Ablation rate variation as a function of the relative humidity.

These experimental results validate the theoretical model above described, indicating the influence of thermo hygrometric parameters on the ablation rate and, as a consequence, a higher risk of under-correction at high values of temperature and relative humidity. Specifically, an overall diminution of about 10% of the ablation rate, reported in the RH range from 35 to 55%, is consistent with the results obtained by the simulations.

Therefore, in order to improve the reliability of RP a device to maintain thermohygrometric parameters constant has been designed.

IV. DEVICE LAYOUT

The device helps keeping temperature and relative humidity in the volume of air between the laser source and the cornea, independent from room environmental conditions (Device Anti-Environmental Changes = DAEC).

As showed in figure 5, DAEC is composed by a fan, a Peltier thermoelectric heat pump and a hose circuit to convey the conditioned air to the control volume. The hose is placed in contact with the cold side of the Peltier heat pump in order to obtain the cooling and the dehumidification of the air. The condensed water is then collected in a condense trap and the air is heated-up with the warm side of the heat pump. The DAEC has been designed in order to keep temperature values within 20±2°C and relative humidity within 55±3% in the control volume.

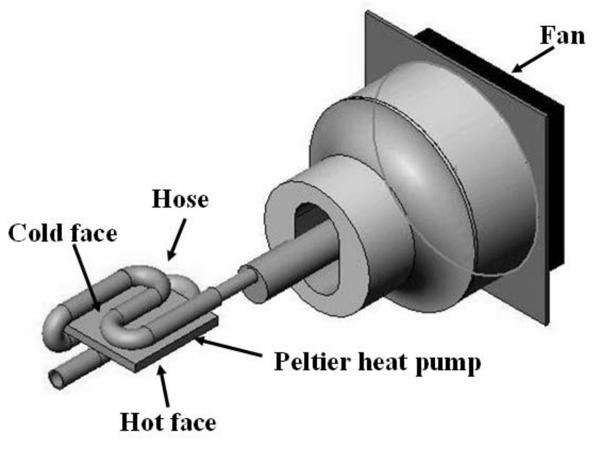

Fig. 5. Schematic of the DAEC to keep constant thermo hygrometric conditions in the control volume.

Environmental conditions may vary in a large range, i.e. from 15 to 35°C and from 55 to 95% RH, the air conditioner is controlled by varying the air flow rate through the supply voltage of the fan and the power of the Peltier heat pump.

A temperature and humidity transducer is placed in the control volume in order to supply the feedback signals of the target thermohygrometric conditions. The entire system is powered by a 9 V battery and is adaptable to any commercial excimer laser.

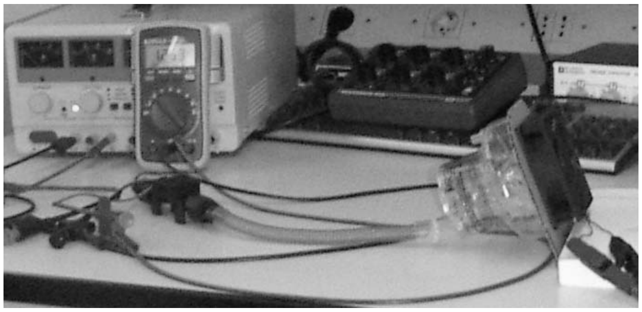

Fig. 6. DAEC prototype.

A series of experiments conducted with a device prototype, (figure 6), showed that the desired values of temperature and relative humidity in a control volume of about 8.8 liters can be obtained in 132 seconds with a flow rate of about 70 $ml \cdot s^{-1}$.

Such a flow rate value corresponds to 5.3 $cm \cdot s^{-1}$ air speed above the cornea. The above value has to be minimal in order to avoid intraoperative dehydration of corneal surface which could lead to poor corneal smoothness. For this reason, higher time to reach steady thermohygrometric conditions must be allowed.

V. CONCLUSIONS

The influence of thermohygrometric parameters on photorefractive excimer laser procedures has been theoretically assessed through a mathematical model. Environmental thermohygrometric factors may influence the outcome of refractive surgery procedures absorbing up to 32% of laser fluence.

A cost-effective conditioning device has been designed in order to keep constant thermohygrometric parameters of the excimer laser beam surrounding air during procedures. This device can be easily adapted to most commercially available excimer lasers.

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REFERENCES

[1] I. R. de Souza, A. P. de Souza, A. P. de Queiroz, P. Figueiredo, R. S. Jesus, N. kara-Jose, "Influence of temperature and humidity on laser in situ keratomileusis outcomes". *J Refract Surg*.,vol. 17 (2 Suppl), pp. S202-204, Mar-Apr 2001

[2] K. A. Walter, A. W. Stevenson, "Effect of environmental factors on myopic LASIK enhancement rates" *J Cataract Refract Surg*.,vol. 30, no. 4, pp. 798-803, Apr 2004

[3] P.M. Pesando, M.P. Ghiringhello, P. Tagliavacche, "Excimer laser in situ keratomileusis for myopia". *J Refract Surg*.,vol. 13, pp. 521-527, Sep-Oct 1997

[4] W. J. Kessler, K. L. Carleton, W. J. Marinelli, " Absorption coefficients for water vapour at 193nm from 300 to 1073 K". *J Quant Spectrosc Radiat Transfer*, vol. 50, pp. 39-46, 1993.

[5] T. Seiler, P.J. McDonnell, "Excimer laser photorefractive keratectomy". *Surv Ophthalmol*, vol. 40, pp. 89-118, Sep-Oct 1995.

[6] G. H. Pettit, M. N. Edinger, R. P. Weiblinger, "Argon fluoride excimer laser ablation of cornea". *Proc. SPIE,* vol. 1646, pp. 236-241, 1992.

[7] M. S. Kitai, V. L. Popkov, V. A. Semchishen, A. A. Kharizov. "The physics of UV laser cornea ablation*". Quantum Electronics, IEEE Journal of,* vol. 27, pp. 302-307, Feb. 1991.