The role of the debris suction system in the physical changes of the corneal surface during refractive excimer laser eye surgery

PhD thesis

by

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1. INTRODUCTION

The corneal surface is reshaped by 193 nm wavelength, ultraviolet-range laser pulses during the refractive correction of the cornea. The thickness of the photoablated tissue depends on the attempted correction measured in diopters. The micrometer-precise positioning of the laser beam is able to reshape the surface, which gives the opportunity to correct the myopic, the hyperopic, the astigmatic, the compound astigmatic and even the higher order refractive differences as well.

The 193 nm wavelength laser beam is produced by excimer laser device. The modern, high-frequency laser equipment is able to emit up to 1000 pulses to the cornea in every seconds. The physical phenomenon, which happens when the ultraviolet beam is hit and absorbed in the corneal surface, is called photoablation. Only a part of the high energy density can cause thermal load of the corneal tissue, the other part destructs directly the inter- and intramolecular bindings. Therefore neither the thermal damage of the tissue, nor burning, carbonization or coagulation effects are caused. Tissue steam or debris is created from the molecular fragments breaking down from the surface during the photoablation. The energy of the next arriving laser pulses may be partly shielded, scattered and absorbed during the transmission through this smoke cloud, which results the decrease of the effectivity of the following laser spot. The manufacturer-designed debris suction equipment, which is part of the functional unit of the laser devices are able to produce airflow around the operational surface and to remove the debris. It can decrease or eliminate the shielding, scattering and absorption effect of the smoke plume. At the same time the tissue residue mixed with the air of the operation theatre is reduced, which results the improvement of the comfort of the medical staff and the patient as well.

At the same time the flowing air causes cooling effect, which increases the thermal convection and reduces the warming of the cornea. Beside that the heat balance of the corneal tissue depends on: the internal conduction; the heat radiation of the surface; the hydration of the cornea; the humor and the humoral circulation; and the fact that the tissue volume, which has higher thermal load during the ablation, is breaking down from the surface during the ablation procedure.

Consequently from the above, the predictability of the outcome requires the preciseness of the laser equipment; the positioning, centering and energy distribution of every pulses; the eye movement tracking; and almost every technical parameter of the laser devices. Therefore the manufacturers prescribe regular, hourly, daily, weekly and monthly maintenances and tests, which should be performed by authorized and trained technicians and service engineers.

The polymethyl methacrylate (PMMA) plate is worldwide used to test and validate excimer laser devices. The ablated patterns on the PMMA plates are measured and analyzed with micrometer precision.

2. OBJECTIVES

The objectives of the PhD thesis are related to the examination of the effects of the air flow resulted of the evacuation unit of the laser devices. Three objectives are defined, and performed 1-1 series of measurements to each of them.

1, Is it possible to measure the temperature increase of the cornea during clinical circumstances? If yes, how much is it? Is there a dependency between this temperature increase and the type of the laser platform? This is the topic of the № I. Measurement series.

2, Does the temperature increase depending on the energy of the laser beam and the debris suction? The № II. Measurement series examines that.

3, Does the speed of the air flow have an effect through the shielding, scattering and absorbing of the laser beam to the extent of the ablation? Is it possible to describe it mathematically? The № III. Measurement series deals with this.

By the determination of the objectives the examiner strived to perform all measurements under clinical condition if it was possible, without influencing the postoperative results.

3. METHODS

Patients and methods

The excimer laser devices used to the measurements and the refractive treatments were in good clinical condition with factory settings

The change of the corneal temperature was examined during routine refractive laser treatment in the № I. Measurement series. The operational conditions were not influenced by the measurement with infrared thermometer; therefore it was possible to measure in-vivo, during routine refractive laser treatment. Measurements were performed with three different laser platform, on one eye of 30 patients each of them. Results were analyzed and compared to each other. Surface temperature was measured from 8 cm distance before the treatment, after epithelial removal, just after refractive treatment. The measurement value could be obtained from a 1 cm diameter central area immediately, without delay.

The time dependency of the temperature change was measured in the № II. Measurement series. The two involved laser platforms were in clinical condition state, and high diopter laser treatments were carried out with them. Beam energy was measured with thermoelectric measure head. Temperature measurements were performed with infrared thermometer during PRK treatment, which were performed on the surface of the PMMA plates.

Relationship between the airflow and the photoablation was examined in the № III. Measurement series. Only one laser equipment was enrolled to exclude all other factors except the effect of the air speed to the ablation. The debris suction unit of the laser was modified for this experiment to an adjustable one. PTK treatment profile with 150 μm was ablated to PMMA plates. Nine different airflow speeds were set on the adjustable evacuator equipment. The airflow velocity was measured with anemometer, the ablation depth was measured on the PMMA with contact micrometer.

Instruments

Three laser devices were used in the № I. Measurement series. These are the MEL 70 (manufacturer: Aesculap-Meditec GmBH Jena, Germany), MEL 80 (manufacturer: Carl Zeiss Meditec GmBH Jena, Germany) and Allegretto (manufacturer: Wavelight Inc. Erlangen, Germany).

Author measured on two laser platforms in the № II. Measurement series. These are the Allegretto (manufacturer: Wavelight Inc. Erlangen, Germany) and the Amaris (manufacturer: SCHWIND eye-tech solutions GmBH Kleinostheim, Germany).

In the № III. Measurement series were used the Amaris (manufacturer: SCHWIND eye-tech solutions GmBH Kleinostheim, Germany) laser platform to acquire the measurement data.

The temperature measurements were performed with calibrated, non-contact, infrared EBRO TLC 730 (WTW GmBH, Germany) thermometer. Highly precise (TESTO 405-V1, TESTO GmBH, Lenzkirch, Germany) anemometer was used to acquire the airflow data. The achieved central ablation depth was measured with a calibrated contact micrometer, Inductive Dial Comparator 2000 (Mahr, Göttingen, Germany) with 901 R type standard contact point. The physical principle of the energy measurement instrument was thermoelectric principle, made by Ophir (L30Ex measure head, USB Interface, Ophir Optronics Solutions Ltd., Jerusalem, Israel). The adjustable evacuator was manufactured by Edge Systems Corporations (Redondo Beach, CA, USA) type: Smoke Evacuator.

4. RESULTS

No significant differences were found ($P > 0.05$) between the pre- and postoperative parameters of the patients in the № I. Measurement series. The average of the corneal temperature values are shown on the Figure 1.

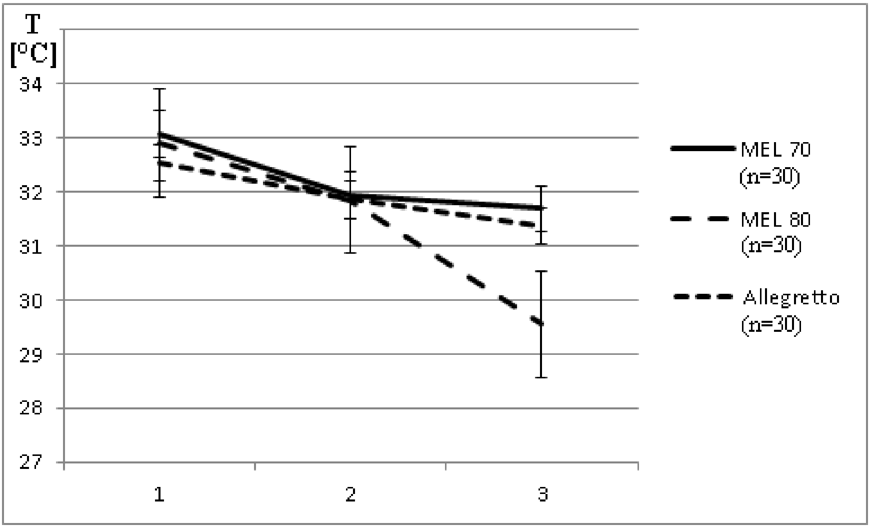

Figure 1. Average corneal temperature by the three laser platform before ephitelial removal (1), after ephitelial removal (2), after treatment (3) (error bar. standard deviation)

The Table 1.shows the measured airflow suction speed on the working plane by the three laser devices, under clinical condition and set with factory settings.

Table 1. Measured airflow suction speed on the working plane under clinical condition of three laser equipment

Laser Platform	Airflow speed [m/s]
Carl Zeiss Meditec MEL 70	0.4
Carl Zeiss Meditec MEL 80	2.2
Wavelight Allegretto	0.15

The temperature changes were calculated, and the duration of the treatments (time factor) was subtracted, speed of the temperature changes in ˚C/min was resulted in to eliminate the effect of the ablation depth. (Table 2.) Average value related to every laser platform were calculated which depend only on the technical parameters of the laser, and does not depends on thickness the ablated tissue.

Table 2. Average value of the temperature exchange by three laser platform, which does not depends on the ablation depth

Laser platform	Calculated value [°C/100µm]
Carl Zeiss Meditec MEL 70	-1.0 ± 1.8 °C/100µm
Carl Zeiss Meditec MEL 80	-4.8 ± 1.6 °C/100µm
Wavelight Allegretto	-1.1 ± 1.1 °C/100µm

According to the one-way ANOVA variance analysis statistically significant differences were found regarding the temperature changes among the different excimer lasers. With the post-hoc Bonferroni test statistically significant difference was found between the MEL 80 laser model and the other two types of excimer lasers (MEL 70 and Allegretto 400 models) ($P < 0.25$). Between the Allegretto and MEL 70 model no difference was found.

Regarding to the postoperative average refraction, there was no statistical difference between the treated groups.

In the № II. Measurement series the one shot energy of the laser beam was measured using two different laser equipment. The repetition rate of the Amaris (500Hz) is 125% higher, than the 400 Hz of the Allegretto, but the output power of the Allegretto is cca. 180% higher, (Allegretto: 620 mW and

Amaris: 350 mW). The treatment time by the Amaris was 140% longer (cca. 40 sec by the Amaris and cca. 29 sec by the Allegretto).

The corneal surface temperatures changes of both lasers are shown on the Figure 2.

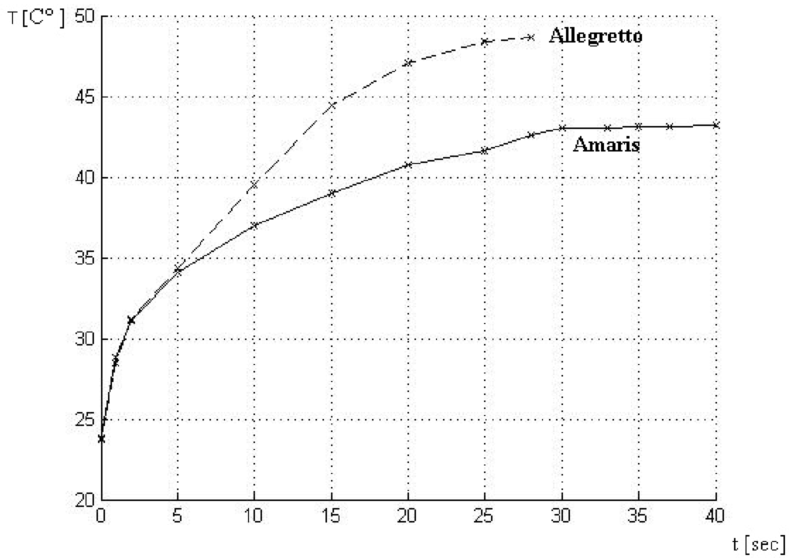

Figure 2. Change of the surface temperature on PMMA by Wavelight Allegretto and Schwind Amaris 500E laser platform

The 48 C° maximum temperature was reached by the end of the treatment. The solid line represents the surface temperature of the PMMA plate during the -10 Dpt treatment by the Amaris. The 43 C° maximum temperature is reached by the end of the treatment as well. The temperature increases faster and higher by the Allegretto, it presents bigger thermal load.

The № III. Measurement series have found relationship between the ablation depth and the airflow speed. Results can be seen on the Figure 3.

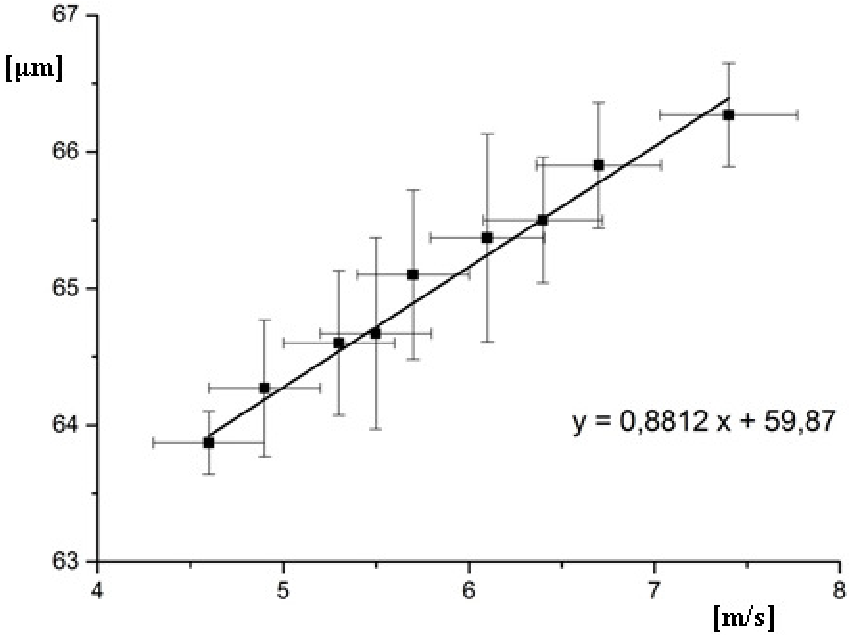

Figure 3. Relationship between ablation depth and airflow speed (error bar: standard deviation)

A simple linear regression was calculated to predict the central ablation depth based on the air velocity. A significant equation was found ($F(1,8) = 552.85$, $p < 0.001$). The results of the regression indicated the velocity explained 98.2% of the variance ($R^2 = 0.982$, $R^2_{adj} = 0.984$)

5. CONCLUSIONS

Preliminary international studies reported usually warming effect of the corneal surface during treatment. The № I. Measurement series resulted in difference among of cooling effect with different laser platforms. This can be explained first of all by the non-contact infrared thermometer. If the measurement distance is 8 cm, the diameter of the measurement area is 1 cm regarding to the factory specification, i.e. the instrument measures in the Total Ablation Zone (TAZ), and apply spatial and temporal averaging. This is the limitation of this measurement principle. Therefore the results of three laser platform in the № I Measurement series were compared to each other, not to the other studies, which used different measurement principles. The other reason of the cooling effect may be derived from the lower temperature and humidity of the operation theatre, which can cause an improved level of the thermal convection. This is confirmed by the fact, that the strongest cooling effect can be measured by the laser platform, which has the strongest airflow speed.

There are many differences in the technical parameters of the three laser platforms. The energy of the laser beam is similar by the Allegretto and the MEL 80, but the repetition frequency is 1.6 times higher by the Allegretto (MEL 80 – 250 Hz; Allegretto 400 Hz), and the suction speed on the working plane is 10 times higher by the MEL 80. Consequently, the calculated value with the °C/100μm unit shows 4 times higher airflow speed by the MEL 80 (MEL 80 -4.8 ± 1.6 °C/100μm, Allegretto -1.1 ± 1.1 °C/100μm). On the other hand, the airflow speed of the MEL 70 is similar to the Allegretto, but the repetition frequency of the MEL 70 differs a lot related to the Allegretto (35 Hz by the MEL 70), i.e. the airflow speed of the suction has an important factor in the cooling effect, and in the thermal balance of the cornea. Therefore the № I. Measurement series emphasized, that the heat balance has a strong dependency on the laser platform, the parameters of the laser beam and the suction.

This statement was confirmed by the two temperature curve resulted in the № II. Measurement series with high diopter (-10 Dpt) PMMA treatment of the two laser platform. The temperatures rise logarithmically in both cases by the long-term test, if the ablation depth i.e. the time of the treatment were long enough to reach the heat balance. The factors of the heat balance explained before reached the equilibrium state, the suction speed; the energy absorption; the thermal conduction, convection and radiation; and the thermal load of the ablated volume were balanced. The one-shot energy of the Allegretto was higher (Allegretto 620 µJ – Amaris 350 µJ), but the repetition frequency was lower (Allegretto 400 Hz – Amaris 500Hz). The measured power on the working plane was 248 mW, and it was 175 mW by the Amaris. Important difference can be measured by the airflow speed on the working plane (Allegretto 0.15 m/s, Amaris 0.4 m/s). Consequently the surface temperature of the PMMA reached a higher level of the heat balance which was 48 °C, meanwhile by the Amaris was 43 °C. It has to be emphasized, that both values can be acquired during the test on PMMA which differs a lot of the parameters of the cornea. It shows the limitations on the usage of PMMA.

The № III.Measurement series examined the relationship between the suction and ablation. Therefore only the suction speed was adjustable, the other parameters, i.e. the repetition frequency, the energy, and the energy distribution were stable. The smoke evacuation unit of the Amaris 500E was modified in this examination by an adjustable airflow speed evacuator.

The calculated percent values measured in the examination showed, that there is a strong relationship between the change of the ablation depth and the velocity of the air flow, and the ablation is predictable with the calculated linear regression from the air flow. The linear regression was $y = 0,8812x + 59,87$ ($R^2 = 0,982$). During the study the ejection of the particles can be observed from the surface and the development of the smoke plume column without evacuation. Increasing the evacuation power this smoke plume column begins to be removed by the evacuation system. A stronger evacuation power results in more evacuated part of the column and reduces the shielding effect. The non-sucked part of the smoke plume can be mixed with the air of the operation room and might reach the sensitivity level of the medical stuff.

The results of the study shows, that the proper settings of the evacuation unit of the laser platform is critical regarding to the wound healing through the stabile temperature condition of the operation room, and again critical regarding to the postoperative refractive results through the proper ablation depth.

Based on the findings of this study, it is recommended to use air flow range of the debris suction determined by the manufacturer, which should be measured and tested periodically by every technical security check (TSC) or Preventive Maintenance (PM) of the laser equipment.

The filter of the evacuation unit is saturated during the frequent usage, therefore the airflow resistance increases, which can lead to decreasing airflow result in speed, i.e. the ablation and the unintended change of the refractive outcomes. The factory-prescribed daily energy fluence test routine calibrations can partially compensate this effect, but this will compensate the consequences only, and not the source of the decrease, which is the shielding caused by the debris. Therefore the regular checking and adjusting of the airflow speed is a strongly recommended, as well as the specification of the factory-tolerated range of the air flow speed. Hence it is not established by every laser platform, author recommends to specify the tolerance range by the manufacturer, and to prescribe protocol to check and adjust periodically the airflow speed of the evacuation system.

New achievements

1. The change of the ablation depth can be predicted from the airflow speed produced by the evacuator system, the calculated linear regression is $y = 08812x + 59.87$ ($R^2 = 0.982$).

2. The proper adjustment and maintenance of the debris suction unit has a critical importance regarding to the postoperative refractive results.

3. The cooling effect of the cornea depends on the thermal convection, which related to the airflow velocity.

4. The specification of the factory tolerated airflow speed range and a protocol of the periodical check and adjustment of the evacuator is necessary with every laser platform.

6. AUTHOR'S PUBLICANTIONS

Publications related to the thesis

Szekrényesi C, Kiss H, Filkorn T, Nagy ZZ

Shielding effect of the smoke plume by the ablation of excimer lasers

BMC Ophthalmology 18: (1) 273 5 p. (2018)

Szekrényesi C, Sándor GL, Gyenes A, Kiss H, Filkorn T, Nagy ZZ

A szaruhártya felszíni hőmérséklete és légáramlási viszonyainak alakulása refraktív célú lézeres beavatkozás közben három különböző típusú és ismétlési frekvenciájú excimer lézerberendezésnél: [Relationship between corneal surface temperature and air flow conditions during refractive laser eye surgery using three different excimer lasers]

ORVOSI HETILAP 157:(43) pp. 1717-1721. (2016)

Szekrényesi C, Sándor G, Gyenes A, Kiss H, Filkorn T, Nagy ZZ

The change of corneal surface temperature during surface refractive surgical procedures performed using excimer lasers with different repetitive frequencies

NEW MEDICINE 20:(3) pp. 81-85. (2016)

Szekrényesi C, Réz K, Nagy ZZ

Surface temperature change of PMMA plates in refractive surgery performed with two types of modern excimer lasers

NEW MEDICINE 20:(4) pp. 126-129. (2016)

Publications independent of the thesis

Gyenes A, Szentmary N, Toth G, Kiss H, Szekrenyesi C, Langenbucher A, Nagy ZZ

Crosslinking kezelés hatása a szaruhártya hámosodására.

ORVOSI HETILAP 158:(10) pp. 376-379. (2017)

2016

Dió M, Szekrényesi C, Zakár I, Zombory P

A biofizika és orvostechnika alapjai

Budapest: Semmelweis Egyetem Egészségtudományi Kar, 2013. 538 p.

(ISBN:978 963 9129 93 1)

Köteles F, Szemerszky R, Gubányi M, Körmendi J, Szekrényesi C, Lloyd R, Molnár L, Drozdovszky O, Bárdos G

Idiopathic environmental intolerance attributed to electromagnetic fields (IEI-EMF) and electrosensibility (ES) – Are they connected?

INTERNATIONAL JOURNAL OF HYGIENE AND ENVIRONMENTAL HEALTH 216:(3) pp. 362-370. (2013)

Gyenes A, Szekrényesi C, Holzer MP, Ehmer A, Auffarth GU, Németh J, Kovács I, Nagy ZZ

Pentacam rotációs Scheimpflug-kamera mérési pontossága keratoconusban

SZEMÉSZET 149:(2) pp. 75-81. (2012)

Végső B, Fülöp K, Kozmann G, Magos T, Szekrényesi C, Nagy Z

Az agyi forrás-lokalizáció pontosságát befolyásoló tényezők vizsgálata

IME: INTERDISZCIPLINÁRIS MAGYAR EGÉSZSÉGÜGY / INFORMATIKA ÉS MENEDZSMENT AZ EGÉSZSÉGÜGYBEN 9:(5) pp. 43-46. (2010)

Nagy Z, Végső B, Magos T, Szekrényesi C, Fülöp K, Kozmann G

A motoros működés agykérgi szerveződésének vizsgálata bioelektromos képalkotó módszerekkel, 128 csatornás nagy felbontású EEG alkalmazásával egészséges személyeknél és stroke-ot követően

IME: INTERDISZCIPLINÁRIS MAGYAR EGÉSZSÉGÜGY / INFORMATIKA ÉS MENEDZSMENT AZ EGÉSZSÉGÜGYBEN 8:(Klnsz) pp. 5-7. (2009)