

Effect of Hinge Position on the Outcome of Laser In Situ Keratomileusis

Thesis

Submitted in Fulfillment of M.D. Degree in Ophthalmology

BY

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List of Abbreviations

ACS: Automated Corneal Shaper
ALK: Automated Lamellar Keratoplasty
ArF: Argon Fluoride
BCVA: Best-Corrected Visional Acuity
BKS: Barraquer- Krumeich- Swinger microkeratome
D: Daiopter
DEWS: Dry Eye Workshop
DLK: Diffuse Lamellar Keratitis
EGF: Epidermal Growth Factor
FDA: Food and Drug Administration
FPD: Freezing Point Depression
H₂O: Hydrogen Di-Oxide (Water)
HGF: Hepatocyte Growth Factor
Hrs: Hours
ICR: Intrastromal Corneal Ring
IOP: Intraocular Pressure
KCS: Kerato-Conjunctivitis Sicca
Km/s: Kilometer per second
LASIK: Laser in-situ keratomileusis
LINE: LASIK-Induced Neurotrophic Epitheliopathy
mm: millimeter
mmHg: millimeter Mercury
mOsm/L: milliosmol per liter
P value: Probability value
PRK: Photorefractive keratectomy
PRT: phenol red test
PTK: Phototherapeutic keratectomy
RK: Radial Keratotomy
S.Eq: Spherical Equivalent
SD: Standard Deviation
Sec.: Second
SPSS: Statistical Package for the Social Science
SRI: surface regularity index
TBUT: Tear Break-up Time
TMS-BUA: Topographic Modeling System – Break up Area
TMS-TBUT: Topographic Modeling System – Tear Break Time
TMS: Topographic Modeling System
UCVA: Un-Corrected Visional Acuity
UV: Ultraviolet
VEIC: Vardinoyannion Eye Institute of Crete
μL: Microliter
μm: micrometer
°C: degree centigrade

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Introduction and Aim of work

Introduction

Laser in-situ keratomileusis (LASIK) involves creating a corneal flap so that midstromal tissue can be ablated directly and reshaped with an excimer laser beam. The procedure allows the ophthalmologist to surgically reshape the cornea in an attempt to obviate the need for corrective lenses (**Pallikaris et al., 1990 [a]**).

LASIK is a modification of Colombian José Barraquer's ingenious innovations. In 1949, Barraquer first described his technique (**Barraquer, 1949**), and in 1964 he published clinical results of his attempts to achieve emmetropia by shaving and reshaping the cornea. With Barraquer's technique of keratomileusis (i.e., carving the cornea), a lamellar button (lenticule) of the patient's cornea was excised with a manual microkeratome. Barraquer then reshaped the lenticule so that the central corneal curvature was flattened and the refractive power of the cornea decreased. He then replaced the lenticule in position, either with or without sutures. Barraquer's specific attempts to correct myopia were called cryolathe keratomileusis, because they involved freezing and reshaping the removed lenticule with a cryolathe (**Barraquer, 1964**).

The term *excimer* has been coined by **Stevens and Hutton in 1960** (short for excited dimer) to describe an energized molecule with two identical components. The name *excimer* was applied to noble gas-halide laser and persisted even though it is a misnomer (The lasing medium is a combination of two different elements, a noble gas and a halide, rather than a dimer). More accurate but less popular names including

rare gas halide lasers, which describes the gas mixture in the cavity and the name of the specific gas mixture (eg., *Argon-fluorine laser*) (**Shalash et al., 1997**).

Excimer is capable of precise ablation of corneal tissue with minimal disruption of adjacent tissue. The *excimer* laser's effect on the cornea was first studied in animal models in 1983 (**Trokel et al., 1983**). In 1985, Serdarevic and co-workers performed the first PTK (Phototherapeutic keratectomy) using Excimer laser (**Serdarevic et al., 1985**). The term PRK (Photorefractive keratectomy) was created in **1985 by Marshal et al.** The first PRK was done on a blind eye by Seiler in Berlin, Germany (**Seiler et al., 1986**), and the first PRK on a sighted human eye was performed in May 1988 in United States by Marguerite McDonald at Louisiana State University (**McDonald et al., 1989**). Shortly thereafter, LASIK (Laser in-situ keratomileusis) was done in human eyes (**Pallikaris et al, 1990 [a]**). This early work supported the theory that in situ keratomileusis was better than surface ablation because it induced less activation and proliferation of stromal keratocytes, thereby avoiding both haze and regression (**Park and Kim, 1999**). In addition, the excimer laser allowed for more accurate tissue removal, thereby eliminating one of the main deterrents to lamellar surgery (**Glazer and Azar, 2003**).

The LASIK procedure, in its current refined state, was designed and developed at the University of Crete. In 1990, Ioannis Pallikaris and colleagues introduced the term laser in situ keratomileusis (LASIK) to describe excimer laser ablation performed under a hinged corneal flap (**Pallikaris et al., 1990 [a]**).

In LASIK the automated microkeratome is used to create a hinged corneal disc (i.e., flap), which consists of epithelium, Bowmans layer and anterior stroma. The laser beam is then applied directly to the stroma, to remove a predetermined amount of tissue, depending on the target correction. Once ablation is completed, the flap is repositioned and held in place with the action of the endothelial pump. The idea for the LASIK procedure was based on the histological observation that during surface photoablation (PRK) the corneal neural network is also ablated and takes several months to reconstitute. The initial hypothesis was that destruction of both Bowman's layer and the superficial corneal nerves during PRK would have an adverse effect on the healing response. It was thus theorized that creation of a flap instead of a lamellar disc would assure better fitting of tissues after the ablation and would not affect the anatomic integrity of the cornea mainly by preserving Bowman's layer and the superficial corneal nervous net. Other important advantages would be reduction of surgical manipulations and total time required for the operation **(Pallikaris et al., 1990 [a])**

As the use of the excimer laser in refractive surgery increased, it became obvious that wide area surface PRK was neither predictable nor accurate for the correction of more than 6 diopters of myopia **(Seiler and Mc Donnell, 1995)**. Thus, in the beginning, LASIK was suggested as a more precise alternative for the correction of high myopia. To date, several clinical studies published in peer-reviewed journals point out its advantages over PRK **(Bas and Onnis, 1995. Salah et al., 1996. Perez-Santonja et al., 1997. Ibrahim, 1998. Lavery, 1998. Zaldivar et al., 1998)**. These include: Early recovery of visual function, Minimal postoperative pain, Lack of adverse healing phenomena such as haze formation, Increased range of efficacy over PRK in high

myopia, hyperopia, and astigmatism and the ability to combine with previous refractive surgery such as PRK, PTK or RK.

However, the technique has also well-recognized disadvantages and limitations. These include: Expense and complexity of instrumentation, lack of a standardized nomogram for tissue ablation and steep learning curve and potentially sight-threatening complications for the beginning surgeon (**Farah et al., 1998**).

A review of bibliography on LASIK by Farah and coauthors suggests that LASIK is the best procedure to correct myopia greater than 6 D. It has acceptable visual outcomes and complication rates. It also appears effective for lower levels of hyperopia below 6 D (**Farah et al., 1998**).

Several studies highlight that LASIK can cause sustained dysfunction of the integrated ocular surface/lacrimal gland functional unit, resulting in chronic dry eye (**Battat et al, 2001**). In 2001, 2003 and 2004 surveys of members of the American Society of Cataract and Refractive Surgeons, they all found that the most common complication of LASIK was dry eye (**Solomon et al, 2002. Solomon et al, 2004. Sandoval et al, 2005**). LASIK is not the only corneal procedure that might affect tear production, as in 2002, Kessler and co-workers found that there was transient dry eye following Intacs placement, but the tear film quality was restored within 1 week of surgery (**Kessler et al., 2002**).

Pre-operative evaluation of patients should include assessment of tear film quality and breakup and corneal epithelial integrity is mandatory. Patients with evidence of corneal staining should be treated preoperatively. Management may include topical lubricants, punctal occlusion, and occasionally oral doxycycline if the patient has evidence of meibomian gland dysfunction (**Braunstein et al., 2003**).

Aim of The Work

The purpose of this study is to prospectively compare the different outcome parameters in patients undergoing myopic LASIK who were randomly allocated to nasal hinge or superior-hinge flaps. Another objective of this study is to determine the significant risk factors for developing dry eye and its correlation with corneal sensation.