ACCURACY AND REPRODUCIBILITY OF FLAP THICKNESS WITH THE VisuMax® FEMTOSECOND LASER SYSTEM

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A prospective non-comparative study to measure the accuracy and reproducibility of central flap thickness for flaps created with the VisuMax® femtosecond laser system.

INTRODUCTION

Microkeratomes are used in laser in situ keratomileusis (LASIK) to create a corneal flap of a desired thickness. The accuracy and reproducibility of flap thickness influence the ability to predict the residual stromal thickness (RST), and as a consequence directly affect the safety and efficacy of the procedure[1, 2]. The cornea is thinnest centrally and the ablation of a myopic profile is deepest centrally, therefore the central flap thickness is particularly important when considering residual stromal thickness. High variability in flap thickness can increase the risk of long-term plastic corneal changes, such as ectasia, in cases where a flap was significantly thicker than expected[1-3]. On the other hand, if a flap was thinner than expected, there is the risk of obtaining button holes[4]. Variability in flap thickness can also have a direct effect on refractive correction because the depth of keratectomy relates to the amount of intraoperative bioelastic corneal change, which in turn affects the accuracy of the desired curvature change[5].

Flap thickness standard deviation of certain mechanical microkeratomes was in the range of 20 to 40 µm[6-12]. More recent mechanical microkeratomes have improved flap thickness standard deviation to between 12 and 20 µm[2, 13, 14].

Recently, femtosecond lasers have been used for flap creation with a view to further improving the accuracy and reproducibility of flap thickness. At this time, a number of femtosecond lasers are commercially available: the IntraLase femtosecond laser (Intralase Corp, Irvine, California), the Femto LDV (Ziemer Ophthalmic Systems AG, Port, Switzerland), the Femtec femtosecond laser (20/10 Perfect Vision, Heidelberg, Germany) and the VisuMax® femtosecond laser system (Carl Zeiss Meditec, Jena, Germany). The published flap thickness standard deviation of femtosecond lasers varies between 5 µm[15] and 19 µm[13], with an average of approximately 12 µm[13-20].

The VisuMax® femtosecond laser system obtained CE mark approval and was granted clearance to market by the U.S. Food & Drug Administration (FDA) in January 2007. The purpose of this study was to measure the accuracy and reproducibility of central flap thickness for flaps created with the VisuMax® femtosecond laser system.

METHODS

Patients

This study was a prospective non-comparative cases, series of patients recruited from a population of patients seeking refractive surgery at the London Vision Clinic, London, UK. A complete ocular examination was performed to screen for corneal abnormalities and determine patient candidacy for refractive surgery.

The subjects included for the study were myopic with a spherical equivalent up to −6.50 D. Patients with ocular pathologies such as keratoconus, corneal scars, corneal dystrophies, and previous ocular surgery were excluded. Preoperative assessment included manifest refraction, log MAR BSCVA (CSV-1000 Vector Vision Inc, Greenville, Ohio, USA) and cycloplegic refraction using one drop of Tropicamide 1% (Alcon Laboratories UK, Ltd, Hemel Hempstead). Contrast sensitivity was measured with the CSV-1000. Topography and keratometry were assessed using the Orbscan II (Bausch & Lomb, Salt Lake City, Utah, USA) and the Atlas® (Carl Zeiss Meditec, Jena, Germany). Dynamic pupillometry was carried out using the Procyon P2000 pupillometer (Procyon Instruments, London, UK).

Wavefront assessment was performed using the WASCA™ aberrometer (Carl Zeiss Meditec AG, Jena, Germany). Single-point hand-held pachymetry was measured with the Corneo-Gage Plus (50 MHz) ultrasound pachymeter (Sonogage, Cleveland, Ohio, USA). The white-to-white diameter was obtained from the Orbscan examination. Layered pachymetry of the cornea for the central 8–10 mm diameter was obtained using the Artemis 1 very high-frequency digital ultrasound arc scanner (ArcScan Inc., Evergreen, Colorado).

A written informed consent was obtained from the subjects. The study adhered to the tenets of the Declaration of Helsinki and was performed in accordance with an Institutional Review Board approved protocol.

VisuMax® Femtosecond Laser System

The method of operating the VisuMax® femtosecond laser is similar to mechanical and other femtosecond microkeratomes. The eye is applanated to a contact glass and suction is applied. While the eye is immobilized, the flap is created. The main difference in applanation with the VisuMax® is that suction is applied to the cornea and limbus rather than onto the bulber conjunctival sclera, which means that the suction required is very low. The contact glass also has a curved surface so that the eye does not need to be applanated to a flat surface. The combination of the curved contact glass and low suction means that the patient can see throughout the procedure and a blinking green light is used for fixation. The manifest refraction can be entered into the VisuMax® to automatically adjust the internal optics to focus the fixation target for each individual eye. The patient's keratometry is also entered into the VisuMax® to calculate the laser focus depth in the peripheral cornea. The contact glass is available in three sizes; small (S), medium (M), and large (L). The size of the contact glass is chosen depending on the limbus diameter. Flap parameters that can be adjusted include the flap thickness, flap diameter, hinge width, sidecut angle and hinge location.

Surgical Procedure

All procedures were performed by the same surgeon (DZR). A few drops of proxymetacaine 0.5% (Chauvin Pharmaceuticals Ltd, Surrey, UK) were instilled to anaesthetize the eye. The VisuMax® was pre-programmed for each procedure with a flap thickness of 110 µm, a flap diameter of 8.5 mm, a hinge width of 3.5 mm, a sidecut angle of 110°, and a superior hinge. The manifest refraction and keratometry were entered into the VisuMax®. The S size contact glass was used for one patient whose Orbscan white-to-white diameter was 11.4 mm. The M size contact glass was used in all other patients.

The patient was told to fixate on the green light while the surgeon controlled the patient bed to align the patient and raise them towards the contact glass. The surgeon observed the alignment of the applanation through the operating microscope until the cornea was applanated outside the desired flap diameter and no fluid meniscus was evident. The applanated cornea was further aligned to center the planned flap diameter on the corneal vertex, and the laser treatment was delivered by the surgeon pressing on a foot pedal. Flap creation time was approximately 40 seconds for each eye.

After the surgeon concluded creating the flap, the patient bed was rotated 180° to be positioned under the MEL 80™ excimer laser (Carl Zeiss Meditec, Jena, Germany). There was little to no trace of residual bubbles by the time the patient was positioned under the MEL 80™ and eye tracker operation was instant. The flap was lifted and laser ablation was carried out.

Postoperative Evaluation

Patients were instructed to wear plastic shields at night for 7 nights. Tobradex (Alcon, Fort Worth, TX, USA) and Exocin (Allergan Ltd, Marlow, UK) were applied four times daily for the first week. Patients were reviewed at one day, one week, one month, and three months. All postoperative follow-up visits included measurement of manifest refraction, uncorrected visual acuity (UCVA), best-corrected visual acuity (BSCVA), Orbscan II topography, WASCA™ aberrometry, contrast sensitivity, Visante™ OCT optical coherence tomography (Carl Zeiss Meditec, Jena, Germany) and Artemis I VHF digital ultrasound.

Original Flap Thickness Measurement

Central original flap thickness was measured with the Artemis 1 by adding the thickness of the stromal component of the flap, measured 3 months after surgery, to the preoperative epithelial thickness[21]. Measuring the flap at least 3 months after surgery ensures that postoperative edema has resolved, while using the preoperative epithelial thickness accounts for any postoperative epithelial changes known to occur after LASIK[5, 22]. There might still be flap thickness inaccuracies as biomechanical changes in the flap were not considered. The details of the scanning system and patient setup have been described previously[23]. The repeatability of single-point flap thickness measurements using the Artemis I VHF digital ultrasound arc-scanning system has been shown to be 1.14 µm[23].

Statistical Analysis

Descriptive statistics (mean, standard deviation, minimum, maximum, and range) were calculated for the central original flap thickness across eyes. Accuracy of original flap thickness was calculated as the difference between the mean and the intended flap thickness (110 µm in this case series). Reproducibility of original flap thickness was evaluated as the flap thickness standard deviation between eyes.

RESULTS

Twenty-four eyes of 12 patients were included in the study. Patients were examined at 1 day, 1 week, 1 month, and 3 months after surgery with 100 % follow-up for all visits. The population mean age was 31.6 ± 7.5 years, median 30.0 years, ranging from 23.9 to 52.1 years. The mean refraction was −2.98 ± 1.66 D sphere (range +0.25 to −5.75 D), and -0.80 ± 0.55 D (range 0.00 to −2.00 D) cylinder. The mean spherical equivalent was −3.40 ± 1.63 D (range −0.75 to −6.00 D). Keratometric power and central corneal thickness were within commonly found ranges for myopes. The mean keratometric power was 44.88 ± 1.63 D (range 41.80 to 48.80 D) in the steep meridian and 43.97 ± 1.47 D (range 41.40 to 47.20 D) in the flat meridian. The mean central corneal thickness was 528.4 ± 27.4 µm (range 483 to 572 µm). The BSCVA was 20/20 in 37.5 % of eyes, 20/16 in 50.0 % of eyes and 20/12.5 in 12.5 % of eyes.

The mean central original flap thickness at 3 months for all eyes was 112.3 ± 7.9 µm, giving an accuracy of +2.3 µm and reproducibility was 7.9 µm. The minimum central flap thickness was 102.6 µm and the maximum central flap thickness was 132.9 µm, giving a range of 30.3 µm. The distribution of central flap thickness for all eyes is presented in Figure 1.

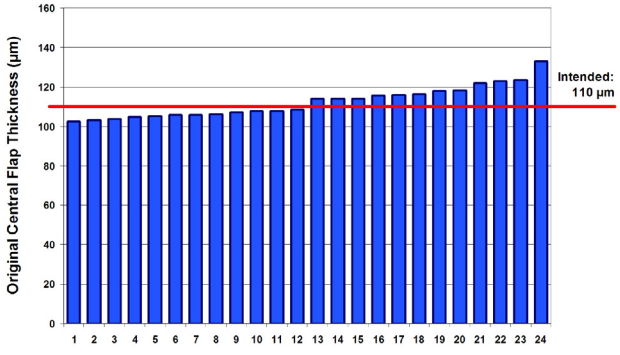

Figure 1: Distribution of original central flap thickness at 3 months post-surgery for eyes treated with the VisuMax®. Measurements are made using the Artemis I VHF digital ultrasound arc-scanning system. Further details are given in the text.

Twenty-five percent of eyes were within 2 µm of the intended flap thickness; 54.2% of eyes were within 5 µm of the intended flap thickness, and 87.5 % were within 10 µm of the intended flap thickness.

CONCLUSION

This is the first study of flap thickness on femtosecond flaps that has been performed using a measurement device with the accuracy and precision to determine if the accuracy and precision is below 10 microns. Clearly with hand-held devices using ultrasound pre- and post-cut there are a number of variables leading to lower accuracy and precision; these include hydration changes in the stroma, localization of the probe to the same point before and after flap creation, and the inherent inaccuracy of these hand-held devices which probably only measure to within 5 to 10 microns SD. Due to the very high accuracy (maximum 3.5 microns error) and precision (maximum 1.2 microns SD) of VHF digital ultrasound scanning, we were able to truly characterize the accuracy and precision of the VisuMax® femtosecond laser system with confidence for values between 5 and 10 microns of accuracy and standard deviation. The VisuMax® was found to produce highly accurate and reproducible flaps; for flaps with an intended thickness of 110 µm, the mean original flap thickness was 112.3 µm and the reproducibility was 7.9 µm. The high accuracy and low flap thickness standard deviation achieved by the VisuMax® should provide surgeons with the confidence to create thin flaps and help to improve the safety and accuracy of the biomechanical changes due to LASIK.

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