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CLINICAL STUDY

Flap characteristics, predictability, and safety of the Ziemer FEMTO LDV femtosecond laser with the disposable suction ring for LASIK

J Pietilä[1,2], A Huhtala[1], P Mäkinen[1,2] and H Uusitalo[2,3]

Abstract

Aims **The outcomes of laser-assisted *in situ* keratomileusis (LASIK) operations performed with the Classic FEMTO LDV femtosecond laser using the plastic single-use suction ring (Ziemer Ophthalmic Systems) and the Allegretto Wave Concerto 500 Hz excimer laser (Wavelight AG) are presented in terms of accuracy, predictability, and safety of the operation.**

Methods **A FEMTO LDV plastic suction ring was used for flap creation in 342 eyes of 179 patients. The intended flap thickness was 90 μm. The size of the suction ring varied from 9.0 to 10.0 mm. Flap dimensions were measured and correlated to preoperative characteristics.**

Results **Mean flap thickness was very constant, 89.6 ± 2.0 μm (range 84–97). In 163 bilateral operations, the second flap was 1.1 μm thinner than the one cut first ($P < 0.0001$). Mean flap diameter was 9.4 ± 0.2 mm (range 8.1–9.9). Mean hinge length was 3.9 ± 0.2 mm (range 3.0–4.2). In hyperopic eyes, flap thickness correlated negatively with keratometric power K_1 and flap diameter. In hyperopic eyes, flap diameter correlated positively with spherical equivalent refraction and with keratometric power K_1 as well as hinge length both in myopic and hyperopic eyes. Complications were reported in 12 (3.5%) eyes. Complications were very mild and none of them prevented further refractive laser treatment. Two Snellen lines of corrected distance visual acuity were lost in one (0.3%) eye.**

Conclusion **The FEMTO LDV plastic single-use suction rings yielded accurate and reproducible flaps and were safe for the creation of thin corneal flaps.**

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Keywords: laser *in situ* keratomileusis; LASIK; femtosecond laser; flap creation; flap thickness

[1]Department of Ophthalmology, Mehiläinen Hospital, Silmäasema Medical Center Tampere, Tampere, Finland

[2]SILK, Department of Ophthalmology, University of Tampere, School of Medicine, Tampere, Finland

[3]TAUH Eye Center, Tampere University Hospital, Tampere, Finland

Correspondence:
A Huhtala, Department of Ophthalmology, Mehiläinen Hospital, Silmäasema Medical Center Tampere, Hämeenkatu 6, 33100 Tampere, Finland
Tel: +358 50 3040458;
E-mail: annemhuhtala@gmail.com

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Introduction

Laser-assisted *in situ* keratomileusis (LASIK) remains to be the most commonly used refractive surgery technique for the correction of myopia, hyperopia, and astigmatism.[1] The first phase of LASIK, the creation of a corneal flap, is the most critical step of LASIK and it affects the visual outcome of the whole procedure. The technological evolution of flap creation has emerged from manually guided mechanical microkeratomes to automated microkeratomes, single-use microkeratomes, and most recently to femtosecond laser technology. There are several femtosecond lasers on the market, including Intralase (Abbot Medical Optics, Irvine, CA, USA),[2–5] FEMTO LDV (Ziemer Ophthalmic Systems, Port, Switzerland),[6] FEMTEC (20/10 Perfect Vision, Heidelberg, Germany),[7] and VisuMax (Carl Zeiss Meditec, Jena, Germany).[8,9] Femtosecond laser technology has been shown to have some advantages in comparison to microkeratome, for example, less variation in flap thickness and a more uniform flap thickness throughout the whole flap compared

with microkeratome-based flap.[2,5,10–12] In the present study, the use of disposable plastic suction ring with the Ziemer femtosecond laser FEMTO LDV was evaluated in 342 eyes in terms of accuracy, predictability, safety, and complications. Recently, disposable suction rings have gained popularity because of microbiological safety to avoid sterilization process.

Patients and methods

Study design

A retrospective, computer-based review of the records of 342 consecutive eyes of 179 patients, who underwent LASIK flap creation with the Classic FEMTO LDV femtosecond laser using the plastic disposable suction ring at Mehiläinen Hospital in Tampere (Finland) between October 2010 and April 2011, was performed. The principles of the Declaration of Helsinki and good clinical practice guidelines were followed. The Ethics Committee at the University Hospital of Tampere declared that this type of a retrospective study waived the need for the Ethics Committee approval, in accordance with the Finnish law on human clinical trials.

All eyes were operated by the same surgeon (JP). In bilateral operations of 163 patients, the right eye was operated first. The same disposable suction ring and intershield was used for the left eye. The eyes were analyzed as myopic or hyperopic groups based on the spherical equivalent refraction (SE); 285 eyes having SE <0.0 D were classified myopic and 57 eyes having SE $\geq +0.0$ D were classified hyperopic.

Preoperative examinations

All patients had a complete preoperative ophthalmologic examination before the LASIK surgery to exclude any severe pathology that might be a contraindication for surgery or have an effect on flap creation. The examination included determination of manifest refraction, measurement of uncorrected and corrected visual acuities, wavefront analysis (Allegro Analyzer; Wavelight AG, Erlangen, Germany), biomicroscopy, fundus examination, measurement of three-dimensional corneal topography (Allegro Oculyzer; Wavelight AG), measurement of intraocular pressure (Nidek Tonoref RKT-7700; Gamagori, Aichi, Japan), and indirect ophthalmoscopy.

Surgical technique

Before the surgery, topical anesthetic oxybuprocain hydrochloride (Oftan Obucain; Santen Oy, Tampere, Finland) was instilled into the operated eyes. An aspirating lid speculum (no. 15961; Geuder, Heidelberg, Germany) was used in most of the eyes. Barraquer wired lid speculum was used in eight small eyes when the cone of the FEMTO LDV femtosecond laser did not fit otherwise. Preoperative corneal thickness was measured with ultrasonic pachymetry (SP-3000; Tomey Corp., Nagoya, Japan). The mean of three pachymetry measurements before and after the flap cut was noted. The corneal flap was cut with the FEMTO LDV as described previously.[6] The aimed flap thickness was 90 μm in all the eyes and was determined with the appropriate intershield. The size of the suction ring was typically 9.5 mm (331 eyes), but was 9.0 mm in 10 eyes and 10.0 mm in one eye depending on the corneal curvature. The size of the hinge width was set to 0.3 mm, which generated approximately 4.0-mm hinge length. Central stromal thickness was measured three times immediately after the flap cut without moisturizing the stromal bed. Flap thickness was then calculated by using the subtraction method. The horizontal white-to-white distance of the eye, flap diameter, and hinge length were measured by a standard caliper. The excimer laser treatment was started immediately thereafter using the Allegretto Wave Concerto 500 Hz excimer laser (Wavelight AG) because typically the FEMTO LDV did not cause any opaque bubble layer (OBL) in the

Table 1 Preoperative characteristics of 342 eyes that received LASIK with the Classic FEMTO LDV and the intended flap thickness of 90 μm

Preoperative characteristic	*Value*
Age range (years)	17–66
Mean patient age (years)	37.7 ± 11.3
Mean spherical equivalent refraction (D)	
Myopic eyes (n = number of eyes)	−4.24 ± 2.19 (285)
Hyperopic eyes (n = number of eyes)	+2.02 ± 1.25 (57)
Mean preoperative keratometric power (D)	
K_1	43.03 ± 1.18
K_2	44.06 ± 1.20
Mean horizontal white-to-white distance (mm)	11.5 ± 0.4
Mean preoperative corneal thickness (μm)	542.7 ± 34.6

Continuous variables are means ± SDs.

Table 2 Postoperative characteristics of 342 eyes that received LASIK with the Classic FEMTO LDV and the intended flap thickness of 90 μm

Postoperative characteristic	*Value*
Range of flap thickness (μm)	84–97
Mean flap thickness (μm)	89.6 ± 2.0
Mean difference from the intended flap thickness (μm)	0.4 ± 2.0
Mean horizontal flap diameter (mm)	9.4 ± 0.2
Mean hinge length (mm)	3.9 ± 0.2

Continuous variables are means ± SDs.

interphase. All complications during the procedure and the 1-month follow-up were recorded.

Statistical analysis

Means and standard deviations for flap thickness, horizontal flap diameter, and hinge length of the operated eyes were calculated. Single variable correlation of flap thickness and preoperative spherical equivalent refraction, corneal thickness, age, keratometric power K_1, flap diameter, and hinge length was evaluated using GraphPad Prism software (GraphPad, San Diego, CA, USA). Myopic and hyperopic subgroups were analyzed separately.

Results

The mean age of 342 patients was 37.7 ± 11.3 years (range 17–66 years). Mean SE in myopic eyes was −4.24 ± 2.19 D (range −0.13 to −12.63 D) and in hyperopic eyes +2.02 ± 1.25 D (range 0 to +5.25 D). Other preoperative characteristics of 342 eyes are presented in Table 1.

Table 3 Correlation coefficients of variables *vs* flap thickness of 342 eyes (285 myopic and 57 hyperopic eyes) operated with the Classic FEMTO LDV

Variable	*Mean ± SD*	*Correlation coefficient*	P-*value*
Spherical equivalent refraction (D)	−3.20 ± 3.12	−0.069	NS
Myopic eyes	−4.24 ± 2.19	0.010	NS
Hyperopic eyes	+2.02 ± 1.25	−0.218	NS
Corneal thickness (μm)	542.73 ± 34.61	0.040	NS
Myopic eyes	543.62 ± 34.16	0.094	NS
Hyperopic eyes	538.26 ± 36.72	0.130	NS
Age (years)	37.71 ± 11.27	−0.138	<0.05[a]
Myopic eyes	35.34 ± 9.53	−0.086	NS
Hyperopic eyes	49.56 ± 11.88	−0.223	NS
K_1 keratometry (D)	43.03 ± 1.18	−0.125	<0.05[a]
Myopic eyes	43.12 ± 1.16	−0.099	NS
Hyperopic eyes	42.61 ± 1.18	−0.333	<0.05[a]
Flap diameter (mm) with a 9.5-mm suction ring (n = 331)	9.43 ± 0.23	−0.069	NS
Myopic eyes (n = 276)	9.45 ± 0.23	−0.044	NS
Hyperopic eyes (n = 55)	9.34 ± 0.22	−0.290	<0.05[a]
Hinge length (mm) with a 9.5-mm suction ring (n = 324)[a]	3.89 ± 0.36	0.190	<0.001
Myopic eyes (n = 269)	3.89 ± 0.38	0.200	<0.01
Hyperopic eyes (n = 55)	3.92 ± 0.16	0.152	NS

Abbreviations: NS, nonsignificant; SD, standard deviation.
[a] All the seven free caps were omitted.

Figure 1 (a) Keratometric power K_1 and flap thickness (μm) in 57 hyperopic eyes treated with the FEMTO LDV single-use suction ring ($r = -0.33$, $P = 0.01$). Mean keratometric power was 42.61 ± 1.18 D. Increasing flap thickness was associated with flatter keratometric power K_1. (b) Flap diameter (mm) and flap thickness (μm) in 55 hyperopic eyes treated with the FEMTO LDV single-use 9.5-mm suction ring ($r = -0.29$, $P = 0.03$). Mean flap diameter was 9.34 ± 0.22 mm. Increasing flap thickness was associated with smaller flap diameter. (c) Hinge length (mm) and flap thickness (μm) in 269 myopic eyes treated with the FEMTO LDV single-use 9.5-mm suction ring ($r = 0.20$, $P = 0.001$). Mean hinge length was 3.89 ± 0.38 mm. Increasing flap thickness was associated with wider hinge length. (d) SE refraction (D) and flap diameter (mm) in 55 hyperopic eyes treated with the FEMTO LDV single use 9.5-mm suction ring ($r = 0.29$, $P = 0.031$). Mean SE was +2.02 ± 1.26 D. Increasing flap diameter was associated with increasing spherical equivalent refraction. (e) Keratometric power K_1 (D) and flap diameter (mm) in 276 myopic eyes treated with the FEMTO LDV single-use 9.5-mm suction ring ($r = 0.38$, $P < 0.0001$). Mean keratometric power was 43.09 ± 1.13 D. Increasing flap diameter was associated with increasing keratometric power K_1. (f) Keratometric power K_1 (D) and flap diameter (mm) in 55 hyperopic eyes treated with the FEMTO LDV single-use 9.5-mm suction ring ($r = 0.31$, $P = 0.022$). Mean keratometric power was 42.56 ± 1.18 D. Increasing flap diameter was associated with increasing keratometric power K_1. (g) Hinge length (mm) and flap diameter (mm) in 269 myopic eyes treated with the FEMTO LDV single-use 9.5-mm suction ring ($r = 0.15$, $P < 0.0001$). Mean hinge length was 3.91 ± 0.18 mm. Increasing flap diameter was associated with increasing hinge length. (h) Hinge length (mm) and flap diameter (mm) in 55 hyperopic eyes treated with the FEMTO LDV single-use 9.5-mm suction ring ($r = 0.30$, $P = 0.027$). Mean hinge length was 3.92 ± 0.16 mm. Increasing flap diameter was associated with increasing hinge length.

The FEMTO LDV plastic suction ring produced very constant flap thickness (Table 2). Mean flap thickness was $89.6 \pm 2.0\,\mu$m (range 84–97 μm). Mean flap diameter was 9.4 ± 0.2 mm (range 8.1–9.9 mm). Mean hinge length was 3.9 ± 0.2 mm (range 3.0–4.2 mm). In bilateral operations, the second flap was 1.1 μm thinner than the first cut flap ($P<0.0001$). Flap diameter in eyes treated with the 9.5-mm suction ring did not differ significantly between the right and the left eye (9.4 ± 0.2 *vs* 9.4 ± 0.2 mm). However, hinge length differed significantly between the right and the left eye (4.0 ± 0.1 *vs* 3.8 ± 0.2 mm, $P<0.0001$).

The correlation coefficients of preoperative characteristics *vs* flap thickness are presented in Table 3. In hyperopic eyes, flap thickness correlated negatively with keratometric power K_1 ($r=-0.33$, $P<0.05$; Figure 1a). The correlations of different flap characteristics were also analyzed and presented in Table 3. Flap diameter correlated negatively with flap thickness in 55 hyperopic eyes that were treated with the 9.5-mm suction ring for flap diameter ($r=-0.29$, $P<0.05$; Figure 1b). Moreover, in 269 myopic eyes treated with the 9.5-mm suction ring, hinge length correlated positively with flap thickness ($r=0.20$, $P<0.01$;

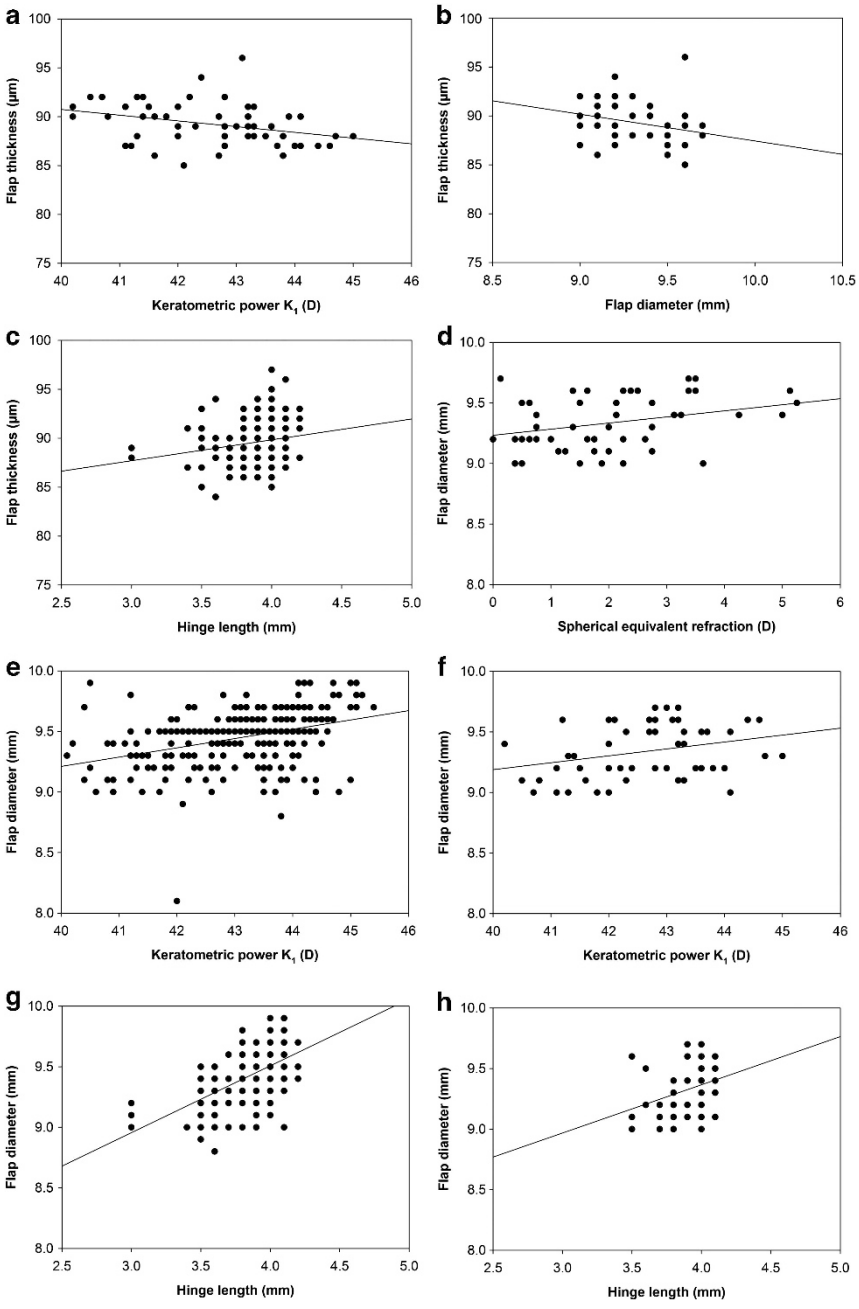

Figure 1c). The correlation coefficients of preoperative characteristics and flap characteristics of the eyes treated with the 9.5-mm suction ring are presented in Table 4. In hyperopic eyes, flap diameter correlated positively with spherical equivalent refraction ($r=0.29$, $P<0.05$; Figure 1d). Moreover, flap diameter correlated positively with the keratometric power K_1 both in myopic eyes ($r=0.38$, $P<0.0001$; Figure 1e) and hyperopic eyes ($r=0.31$, $P<0.05$; Figure 1f). Flap diameter also correlated positively with hinge length both in myopic eyes ($r=0.15$, $P<0.0001$; Figure 1g) and hyperopic eyes ($r=0.30$, $P<0.05$; Figure 1h).

Complications were reported in 12 eyes out of 342 (3.5%) eyes. Intershield problem was reported in two (0.6%) eyes, OBL in two (0.6%) eyes, epithelial defect in one (0.3%) eye, free cap in two (0.6%) eyes, and preserved free cap in five (1.5%) eyes. In preserved free caps, the FEMTO LDV cut a complete flap without a hinge. In those cases, the surgeon opened the free flap so that the hinge of 3–4 mm was preserved. Bleeding occurred in 38 eyes of 342 eyes operated (11.1%). All the complications were regarded as minor and did not prevent the continuation of the refractive surgery with excimer laser.

The safety analysis is based on the follow-up data of 338 eyes after 1 month at the time of the analysis. Two patients (four eyes) were lost in the follow-up. Two Snellen lines of corrected distance visual acuity (CDVA) were lost in one (0.3%) eye and two lines were gained in 2 (0.6%) eyes. In the eye that lost two lines of CDVA an OBL occurred.

Discussion

In 342 eyes treated with the FEMTO LDV plastic single-use suction ring, flap thickness was very constant and averaged $89.6\pm2.0\,\mu$m (range 84–97 μm). In bilateral operations, the second flap was significantly thinner than the first cut flap (right eye $90.1\pm2.0\,\mu$m *vs* left eye $89.0\pm1.8\,\mu$m, $P<0.0001$). This difference of only 1.1 μm is not, however, clinically significant. Mean hinge length averaged 3.9 ± 0.2 mm in both eyes. In our previous study, when we used the reusable FEMTO LDV suction ring in 787 eyes, flap thickness averaged $90.0\pm5.0\,\mu$m.[6] In it, the first and second cut flaps did not differ significantly (right eye $90.0\pm5.5\,\mu$m *vs* left eye $90.1\pm4.6\,\mu$m). Thus, both reusable and disposable suction rings gave similar results for flap characteristics. One limitation of our study was the use of ultrasonic pachymetry instead of online optical coherence pachymetry.[13]

Table 4 Correlation coefficients of variables *vs* flap diameter of 331 eyes (276 myopic and 55 hyperopic eyes) operated with the Classic FEMTO LDV and the 9.5-mm plastic single-use suction ring

Variable	*Mean ± SD*	*Correlation coefficient*	P-*value*
Spherical equivalent refraction (D)	−3.23 ± 3.14	−0.143	<0.01
Myopic eyes	−4.27 ± 2.21	−0.040	NS
Hyperopic eyes	+2.02 ± 1.26	0.291	<0.05
Corneal thickness (μm)	543.10 ± 34.58	0.050	NS
Myopic eyes	543.82 ± 34.15	0.012	NS
Hyperopic eyes	539.47 ± 36.81	0.192	NS
Age (years)	37.66 ± 11.34	−0.112	<0.05
Myopic eyes	35.33 ± 9.64	−0.022	NS
Hyperopic eyes	49.36 ± 12.05	−0.072	NS
K_1 keratometry (D)	43.00 ± 1.15	0.387	<0.0001
Myopic eyes	43.09 ± 1.13	0.379	<0.0001
Hyperopic eyes	42.56 ± 1.18	0.308	<0.05
Hinge length (mm) ($n=324$)	3.92 ± 0.18	0.436	<0.0001
Myopic eyes ($n=269$)	3.91 ± 0.18	0.152	<0.0001
Hyperopic eyes ($n=55$)	3.92 ± 0.16	0.298	<0.05

Abbreviations: NS, nonsignificant; SD, standard deviation.

The overall accuracy and predictability of present study was very good. Therefore, we could find some correlations in which the clinical significance obviously is not very important. Flap thickness correlated negatively with keratometric power K_1 and flap diameter in hyperopic eyes. In these eyes, increasing flap thickness was associated with flatter keratometric power K_1 and smaller flap diameter. In myopic eyes, flap thickness correlated positively with hinge length. Increasing flap thickness was associated with wider hinge length. Increasing flap diameter was associated with increasing hyperopia. Moreover, flap diameter correlated positively with the keratometric power K_1 both in myopic and hyperopic eyes. Flap diameter also correlated positively with hinge length both in myopic and hyperopic eyes.

In our previous study with the FEMTO LDV, we found that achieved flap thickness was slightly dependent on corneal thickness and keratometric value K_1.[6] Increasing flap thickness was associated with increasing corneal thickness and flatter keratometric value. Furthermore, we found that increasing flap diameter was associated with thinner flap thickness in myopic eyes.[6] With the reusable 9.0-mm suction ring, increasing flap diameter was associated with increasing preoperative spherical equivalent refraction in myopic eyes. In all eyes treated with the 9.0-mm suction ring, increasing flap diameter was associated with steeper keratometric value K_1. In hyperopic eyes, increasing flap diameter was also associated with increasing hinge. Using femtosecond laser technology in 1000 consecutive Intralase flaps, Binder[5] found that preoperative corneal thickness or keratometric power did not affect the flap thickness achieved. This difference is due to the technical differences between Intralase and FEMTO LDV not yet known in details.

In the present study, complications were reported in 12 (3.5%) eyes; intershield problem was reported in two eyes, OBL in two eyes, epithelial defect in one eye, free cap in two eyes, and preserved free cap in five eyes. The

intershield problem occurred because the intershield came off the window during the flap cut or at the time when the suction was taken. The laser burned the edges afterwards. These intershield problems occurred although we used sterile water. This usually happens if balanced salt solution (BSS) is used instead of sterile water to apply the foil onto the handpiece. The adhesion force of water is smaller than that of BSS. Therefore, it is important to use sterile water to apply the foil. The OBL in two eyes occurred at the hinge outside the flap margins. These complications were very mild and none of them prevented further refractive laser treatment. In comparison to our previous FEMTO LDV study,[6] the complication rate was 8.4%.

Recommendations and conclusions

Although in this study we used the 0.3-mm hinge width, we recommend changing to the 0.4-mm hinge width to avoid free caps observed in this study. In typical cases, our recommendation is to use the 9.5-mm suction ring. In the cases when the keratometric value K_1 is >46 D, we recommend using the 9.0-mm suction ring. When the keratometric value K_1 is ≤ 41 D, our recommendation is the 10.0-mm suction ring. In the hands of an experienced surgeon, the method of LASIK with the FEMTO LDV combined with plastic single-use suction rings appears to be a predictable and safe procedure that yields flap characteristics very comparable to the reusable suction ring.

Summary

What was known before

- Compared with traditional microkeratomes, femtosecond lasers produce more predictable corneal flaps that are more uniform in flap thickness.
- The Ziemer FEMTO LDV is the only truly mobile, easily transportable femtosecond laser.

What this study adds

- The Classic FEMTO LDV with the single-use suction rings produced large 9.0- to 10.0-mm flaps and thin 90-μm flaps with reproducible flap diameters and flap thickness, respectively.
- In the cases when the keratometric value K_1 is >46 D, it is recommended to use the 9.0-mm suction ring. When the keratometric value K_1 is <41 D, our recommendation is the 10.0-mm suction ring.

Conflict of interest

Dr Pietilä has financial interest in the FEMTO LDV. The other authors declare no conflict of interest.

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