

Thin-flap LASIK with a High-frequency, Low-energy, Small Spot Femtosecond Laser – Effectiveness and Safety

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Abstract

Objective: To evaluate clinical results of a high-frequency, low-energy, small spot femtosecond laser for the creation of thin corneal flaps in laser *in situ* keratomileusis (LASIK) used in a comparative case series at a private practice in Brussels, Belgium. **Methods:** A series of 75 patients selected for LASIK refractive surgery were enrolled for treatment with the Ziemer FEMTO LDV femtosecond laser and received a corneal flap of either 90 μm (59 patients, 103 eyes) or 80 μm (16 patients, 27 eyes) nominal thickness. Prospective evaluation included flap dimensions, intra- and post-operative complications and visual outcomes. **Results:** Mean flap thickness was 89.03 (standard deviation [SD]: $\pm 8.26 \mu\text{m}$) in the 90 μm group and 81.91 (SD $\pm 6.80 \mu\text{m}$) in the 80 μm group. Mean uncorrected visual was 1.19 ± 0.26 in the 90 μm group and 1.10 ± 0.25 in the 80 μm group. Mean manifest refractive spherical equivalent was $-0.12 \pm 0.26 \text{ D}$ in the 90 μm group and $-0.07 \pm 0.31 \text{ D}$ in the 80 μm group. There was no significant visual loss (≥ 2 lines loss of best corrected visual acuity) in either group. One flap tear occurred in the 90 μm group (0.97 %) and two pseudo-buttonholes occurred in the 80 μm group (7.41 %). No other clinically relevant complications occurred intra- or post-operatively. **Conclusions:** The Ziemer LDV femtosecond laser offers a high degree of precision in the creation of 90 and 80 μm flaps for LASIK. Using this device for creating 90 μm flaps can be considered a safe and effective procedure. A higher rate of complications were shown in 80 μm flaps.

Keywords

Laser *in situ* keratomileusis (LASIK), femtosecond laser, thin corneal flaps, 80 μm and 90 μm corneal flaps

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The best flap thickness has traditionally been considered to be 130 μm to 160 μm in order to preserve a greater amount of residual stromal bed (RSB). The demand to correct larger amounts of ametropia, the development of customised ablation techniques with a trend towards enlarging the diameter of laser ablations, the inducement of aberrations by deep lamellar keratectomies and the increasing incidence of post-laser *in situ* keratomileusis (LASIK) corneal ectasia have caused surgeons to reconsider the ideal flap thickness and to develop techniques for achieving thinner flaps.¹

Variability of flap thickness limits the reliability of calculations of RSB, which can be critical in the correction of high myopia or LASIK in eyes with a thin cornea.¹⁻⁵ A thin flap may thus be desirable: it enables the treatment of higher corrections, permits larger ablation zones, induces fewer aberrations, has a lower enhancement rate and better functional results than a conventional $>100 \mu\text{m}$ flap. Moreover, thin flaps help to maximise the RSB – staying further away from the critical 250 μm barrier – and preserve the biomechanical stability of the cornea, hence reducing the risk of ectasia.

A critical prerequisite for thin flaps to be a practical alternative is to use a flap-making modality that creates flaps of uniform and predictable thickness. Femtosecond lasers have been shown to meet this condition

better than mechanical microkeratomes. The practical limits of femtosecond lasers are determined by the mechanical stability and precision of the docking mechanism that applanates the cornea, by the pulse energy, by the capability of the laser optics to focus the laser beam in the cutting plane and finally by the quality of the achieved dissection.

A thinner than conventional flap blends the advantages of lamellar and surface approaches: to preserve as much tissue as possible and at the same time retain an intact flap for fast recovery and protection.^{1,6,7} Sub-Bowman keratomileusis (SBK) is a laser procedure that involves the use of a customised corneal flap between 90 and 110 μm with a diameter that is closely matched to the ablation zone of the excimer laser being used, typically $\pm 8.5 \text{ mm}$.⁸

One of the principal concerns in thin-flap LASIK is that very thin flaps induce the risk of intraoperative complications (pseudo-buttonhole): the thinner the flap, the closer you get to Bowman's layer. Ultra thin flaps are more difficult to handle and more easily displaced enhancing the risk of flap striae and irregular astigmatism.⁹⁻¹¹ Remaining tissue bridges can cause force to be required for separating the flap, which may cause a very thin flap to tear or to over-stretch.

Another concern is the possible occurrence of haze when the flap becomes too thin. The role of the Bowman's layer is important for re-epithelialisation and, if it is absent, activated keratocytes affect collagens causing corneal opacity or haze.¹² This can affect visual recovery, though good functional results have been reported.

Previous studies suggest that LASIK performed with a regular thin flap, made by microkeratome or femtosecond laser, is a safe technique with a very low complication rate. Thin-flap LASIK achieves an excellent predictability of results comparable with the results of conventional LASIK. Moreover it produces better visual results measured as efficacy parameters, a more rapid visual postoperative recovery, a lower rate of enhancements and a better contrast-sensitivity than LASIK with thicker flaps.¹

Flaps made by a femtosecond laser have the additional advantage to be planar and to have less biomechanical impact on the cornea in comparison to mechanically cut flaps.¹³ These flaps have an equal thickness across the entire surface, which results in higher predictability.⁸ The working principle of femtosecond lasers has been described elsewhere.¹⁴

This clinical series used a Ziemer FEMTO LDV femtosecond laser (Ziemer Group AG, Switzerland) for creation of the corneal flap. The FEMTO LDV has the ability to create flaps of 140, 110, 100, 90 and even 80 μm with a very low standard deviation (SD). The flap thickness is determined by the thickness of a plastic sheet (InterShield Spacer, Ziemer Group AG, Switzerland) interpositioned between the laser's applanation window and the cornea. Compared with the flap-cutting outcomes of available mechanical microkeratomers, the FEMTO LDV laser produces thinner flaps and a flap thickness that is more predictable.

One foil is used for each bilateral procedure. A very low pulse energy (less than 100 nanojoules) and short pulse duration (typically 250 femtoseconds) are used. Combined with the high repetition rate and the high pulse overlap this allows a smooth corneal dissection with minimal laser energy being deposited above and below the cutting plane.¹⁵ Compared with other femtosecond lasers, the FEMTO LDV has a faster pulse rate, lower pulse energy and a narrower, more tightly focused beam.

Materials and Methods

Study Design

Between January 2008 and July 2008, 59 patients (103 eyes) with mean age of 37 (range: 23 to 64 years) were treated using a 90 μm InterShield spacer, and 16 patients (27 eyes) with mean age of 37 (range: 20 to 61 years) were treated using an 80 μm InterShield spacer in a private practice in Brussels, Belgium. One foil was used for each bilateral procedure. The cutting performance parameters were optimised with the LDV by altering the slow scan speed in the stroma and for the border cut. The parameters used were 9.5 mm/s for vStroma and 5.0 mm/s for vBorder.

Enrolment Criteria

All patients who qualified for a conventional LASIK procedure were eligible for enrolment in the study. Inclusion criteria were based on calculated RSB $>250 \mu\text{m}$. Eyes with a history of previous corneal procedures (including penetrating keratoplasty, aborted mechanical microkeratome cuts and radial keratotomy) were excluded. The selection of the InterShield Spacer (80 μm or 90 μm thickness) and procedure were randomised.

Clinical Outcomes Measures

Pre-operative assessment included uncorrected distance visual acuity (UCVA) and best corrected distance visual acuity (BCVA), manifest refraction, slit lamp examination, fundus evaluation, scotopic pupil measurement (Procyon P2000, Procyon Instruments, United Kingdom), pachymetry (OLCR (Optical Low Coherence Reflectometer), Haag-Streit AG, Switzerland) and corneal topography (WaveLight Topolyzer and Oculyzer, WaveLight AG, Germany).

Intra-operative analysis included flap diameter (horizontal and vertical), hinge size, flap thickness (Corneo-Gage, Sonogage, Ohio), complications and stromal bed evaluation. Flap dimensions were measured using a Moria caliper. Post-operative assessment included corrected distance visual acuity (CDVA), uncorrected distance visual acuity (UDVA), refractive outcome, slit lamp examination and complications. All visual acuity calculations were performed using minimum angle of resolution (LogMar).

Surgical Technique

Target flap thickness was 90 μm in Group 1 and 80 μm in Group 2. To obtain these flap thicknesses, 90 or 80 InterShield Spacers were used. The target horizontal flap diameter was set by choosing the appropriate 9.5 mm suction ring and programming a 9.5 mm dissection on the control software. The target flap hinge of 4 mm was also programmed. These parameters were not modified according to corneal thickness and/or curvature.

The cornea was wetted with 0.25 % hyaluronate (LaserVis, TRB Chemedica International SA, Switzerland) before application of the femto-laser interface, to ensure a smooth contact between spacer and epithelium and to obtain an even meniscus at the edge of the applanated area. The flap border was marked with Gentian Violet after making the laser cut, to avoid interference of the ink with the laser beam (shadowing).

Micro-bubbles present at the interface disappear immediately when the flap is lifted. Flaps were lifted using a Moria Vryghem spatula 19087. When lifting the flap some moisture can be present on the stromal bed. It is removed with a sponge and the ablation is performed immediately. In this study we used an Allegretto EYE-Q 400 excimer laser (WaveLight AG, Germany) to perform the refractive treatment. In all cases, the optical zone of the ablation was 6.5 mm and the standard nomogram for LASIK was used. The laser room temperature was maintained at 22°C and the relative humidity at 50 %. In all eyes, surgery was planned to leave at least 250 μm of RSB after ablation. After excimer laser ablation, the stromal bed was irrigated and the flap floated back into its original position. Flap alignment was checked using the ink marks, and the flap was checked for proper adherence.

Post-operative Management

Bandage soft contact lenses (SCTL) were used in all patients with an 80 μm dissection and were applied only in case of epithelial defect or free flap in patients with a 90 μm flap. All patients were examined 30 minutes after surgery to check for correct flap position and the presence of interface debris. Post-operative treatment consisted of neomycin sulphate 0.5 % + polymyxin B 5000 IU/ml + prednisolone acetate 0.5 % (Predmycine P, Allergan, California, US) four times a day for 1 week. Ketorolac trometamol 0.5% (Aculare, Allergan, California, US) eyedrops were used as needed as well as frequent instillation of artificial tears: Systane (Alcon, US) or Oxyal (Meda Pharma, Germany).

Post-operative controls were performed at 1 day, 10 days (optional), 6 weeks and 6 months, and included BCVA, manifest refraction, UCVA and slit-lamp examination. In case of pseudo-keratitis sicca, topical cyclosporine and punctum plugs were used at the surgeon's discretion.

Flap Parameters

Target horizontal and vertical flap diameter were 9.5 and 9.1 mm, respectively, with the hinge located superiorly. Hinge size was defined as the width of the uncut portion of the flap. The intended flap thickness of 80 or 90 μm was determined by the thickness of the InterShield spacer interpositioned between the eye and the laser system. Intra-operative flap thickness was calculated using a subtraction method.^{17,18} Pachymetry was performed using the Sonogage (Ohio) Corneogage Ultrasound Plus pachymeter. Stromal bed thickness was considered the lowest of at least five consecutive central corneal measurements. The corneal thickness was measured before flap creation and the stromal bed thickness was measured immediately after flap making (before laser ablation). Flap thickness was computed as the difference between the two measurements.

Data Analysis

Data were stored/analysed using MS Excel (Microsoft Corporation, US).

Results

Pre-operative Parameters

Between January 2008 and July 2008, 59 patients (103 eyes) with a mean age of 37 years (range: 23 to 64) were treated using a 90 μm InterShield spacer, and 16 patients (27 eyes) with mean age of 37 years (range: 20 to 61) were treated using an 80 μm InterShield spacer for thin-flap LASIK correction of myopia. Fewer patients received 80 μm flaps due to potential risks of damaging Bowman's membrane and the need to allow adequate stroma beneath it (see Discussion). There was no significant difference in the pre-operative corneal thickness of both groups. Pre-operative data characterising the two groups are presented in Table 1.

Intra-operative Parameters

Flap Dimensions

In both the 80 μm and the 90 μm groups, mean flap thickness achieved was close to the nominal flap thickness for which the femtosecond laser was set up ($-1.0 \mu\text{m}$ in the 90 μm group; $+1.9 \mu\text{m}$ in the 80 μm group). The mean flap thickness achieved for 80 μm flaps was 81.91 μm (SD: $\pm 6.80 \mu\text{m}$) and for 90 μm flaps was 89.03 (SD: $\pm 8.26 \mu\text{m}$ SD). Intra-operative data are presented in Table 2.

Intra-operative Complications

A few minor complications were noted in the 90 μm group, which were inconsequential for the visual outcome, and not related to the thin flap. These were minor flap adhesions in two eyes (1.94 %). No strong adhesions resulting in difficult flap lifting occurred. One case of flap displacement occurred (0.97 %). Two flaps (1.94 %) showed superior bleeding, due to neovascularisation caused by contact lens wear. Slight decentration was observed in one case (0.97 %) but since the flap size was larger than the ablation diameter, this was inconsequential. Manipulation caused a flap tear in one eye (0.97 %) but there were no other complications. It is notable that none of these complications resulted in a permanent loss of BCVA of 2 lines or more at 6 months follow-up. In one eye (0.97 %) mild epithelial sloughing was noted at the end of the procedure. This could be explained by the friction of the applanation window while trying to establish suction.

Table 1: Pre-operative Parameters

	80 μm Corneal Flap Group	90 μm Corneal Flap Group
Patients (number)	16	59
Age (years)	37 (20 to 61)	37 (23 to 64)
Number of eyes	27	103
Corneal thickness (μm)	530.59 \pm 31.00 (473 to 578)	543.60 \pm 34.70 (445 to 612)
UDVA (D)	-5.57 ± 3.83 (-13.00 to $+2.63$)	-4.28 ± 2.99 (-9.75 to $+4.00$)
Cylinder (D)	-1.49 ± 1.37 (-5.50 to 0)	-0.96 ± 1.09 (-6.00 to 0)
CDVA	-0.09 (-0.18 to 0.05)	-0.12 (-0.18 to 0.16)

Where appropriate, mean \pm 1 standard deviation and range (in parentheses) are given. CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity.

Table 2: Intra-operative Parameters

	80 μm Corneal Flap Group (n=27)	90 μm Corneal Flap Group (n=103)
Flap thickness (μm)	81.91 \pm 6.80 (69 to 94)	89.03 \pm 8.26 (61 to 111)
Deviation from target flap thickness (μm)	+1.91 (-11 to $+14$)	-0.97 (-29 to $+21$)
Horizontal flap diameter (mm)	9.51 \pm 0.29 (8.50 to 9.75)	9.49 \pm 0.22 (8.75 to 10.00)
Vertical flap diameter (mm)	9.10 \pm 0.34 (8.00 to 9.50)	9.11 \pm 0.23 (8.25 to 9.50)
Hinge width (mm)	5.03 \pm 0.51 (3.75 to 6.00)	4.90 \pm 0.64 (3.20 to 6.00)

Where appropriate, mean \pm 1 standard deviation and range (in parentheses) are given. n = number of eyes.

Figure 1: Proportions of Patients Achieving Manifest Refraction Spherical Equivalent (<0.25 D, ± 0.25 D, ± 0.050 D, ± 0.75 D and ± 1.00 D) in the 80 μm and 90 μm Corneal Flap Groups 6 Weeks and 6 Months after Surgery

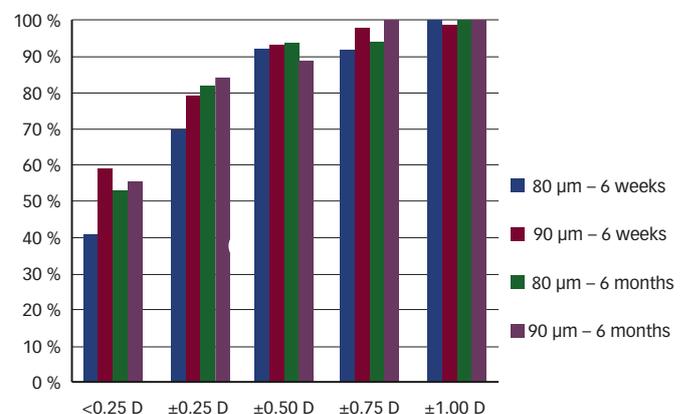
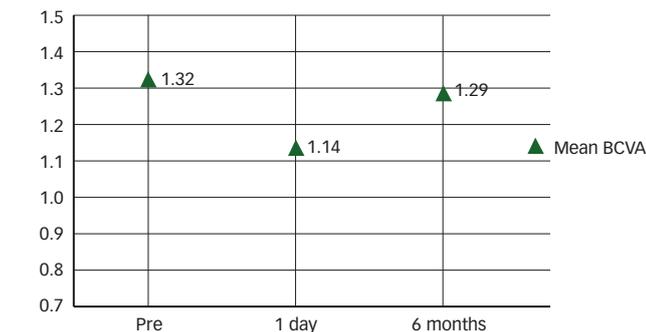


Table 3: Post-operative Parameters

	80 μm Corneal Flap Group		90 μm Corneal Flap Group	
	6 weeks (n=27)	6 months (n=17)	6 weeks (n=103)	6 months (n=65)
Mean	-0.10 ± 0.37	-0.07 ± 0.31	-0.14 ± 0.31	-0.12 ± 0.26
UDVA (D)	$(-1.00$ to $+0.50)$	$(-1.00$ to $+0.38)$	$(-1.75$ to $+0.75)$	$(-0.75$ to $+0.25)$
Mean CDVA	-0.06	-0.04	-0.09	-0.07
	$(-0.18$ to $0.6)$	$(-0.18$ to $0.22)$	$(-0.18$ to $0.16)$	$(-0.18$ to $0.4)$
Cylinder (D)	-0.20 ± 0.31	-0.29 ± 0.30	-0.08 ± 0.22	-0.09 ± 0.17
	$(-1.00$ to $0)$	$(-0.75$ to $0)$	$(-1.50$ to $0)$	$(-0.50$ to $0)$

Where appropriate, mean \pm 1 standard deviation and range (in parentheses) are given. CDVA = corrected distance visual acuity; n = number of eyes; UDVA = uncorrected distance visual acuity.

Figure 2: Post-operative Recovery of Best Corrected Visual Acuity in Patients with 90 µm Corneal Flaps



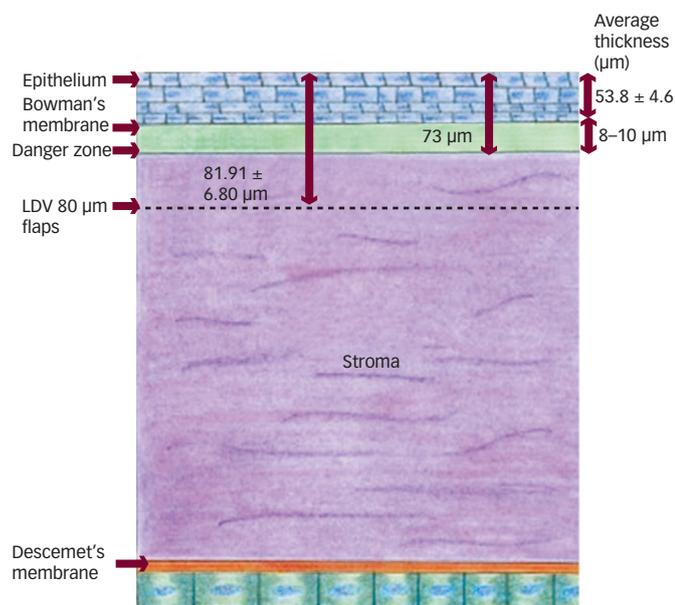
BCVA = best corrected visual acuity.

Figure 3: Post-operative Recovery of Best Corrected Distance Visual Acuity in Patients with 80 µm Corneal Flaps



BCVA = best corrected visual acuity.

Figure 4: Sub-Bowman Keratomileusis Location and Flap Thickness



This incident had no influence on visual performance and was of no significance.

In the 80 µm group, a pseudo-buttonhole occurred in both eyes in one patient and with poor epithelial adhesion. This patient had a pre-operative

pachymetry of 578 µm at the right eye and 577 µm at the left eye. The post-operative follow-up was similar to that of other patients. The patient lost 1 line of BCVA in both eyes probably bound to a slight haze. Other complications did not occur. In this group, the stromal bed appeared rougher, almost like cobblestones. This effect is thought to be due to the higher density of the superficial stroma¹⁹⁻²¹ but has no noticeable visual impact. Bandage SCTL were used in all eyes of the 80 µm group to avoid folds, as these have a tendency to wrinkle when moved.

Post-operative Parameters Effectiveness Measures

In the 90 µm flap group, 6 months after surgery, 65 eyes were available for follow-up (63.1 %). Mean manifest refraction spherical equivalent (MRSE) was -0.12 ± 0.26 D (range: -0.75 to $+0.25$ D) and mean UCVA was 1.19 ± 0.26 (range 0.6 to 1.5). UCVA $\geq 20/25$ was achieved in 93.4 % and $\geq 20/20$ was achieved in 78.7 % of eyes. Levels of ± 0.5 D and ± 1.0 D MRSE were achieved in 89.2 % and 100 % of eyes, respectively (see Figure 1). Post-operative cylinder measures of ≤ 0.25 D and ≤ 0.50 D were achieved in 89.2 % and 100 % of eyes, respectively. The mean post-operative cylinder reading was -0.09 ± 0.17 D (range -0.50 to 0 D). Refractive outcomes after 6 weeks and 6 months are summarised in Table 3.

In the 80 µm flap group, 6 months after surgery, 17 eyes were available for follow-up (62.9 %). The mean MRSE was -0.07 ± 0.31 D (range: -1.00 to $+0.38$ D) and mean UCVA was 1.10 ± 0.25 (range: 0.7 to 1.5). UCVA $\geq 20/25$ was achieved in 94.1 % of patients and $\geq 20/20$ was achieved in only 70.6 % of eyes, largely due to the originally lower quality of vision in these patients. Levels of ± 0.5 D and ± 1.0 D MRSE were achieved in 94.1 % and 100 % of eyes, respectively (see Figure 1). Post-operative cylinder measures of ≤ 0.25 D and ≤ 0.50 D were achieved in 52.9 % and 88.2 % of eyes, respectively. The mean post-operative cylinder amount was -0.29 ± 0.30 D (range: -0.75 to 0 D). Refractive outcomes after 6 weeks and 6 months are summarised in Table 3.

Safety Measures

In the 90 µm group, at 6 months after surgery the mean BCVA was 1.29 ± 0.18 (range: 0.8 to 1.5). Significant visual loss (≥ 2 lines loss of CDVA) did not occur. Post-operative recovery of BCVA in this group is demonstrated in Figure 2. In the 80 µm group, 6 months after surgery, the mean BCVA was 1.26 ± 0.20 (range: 0.9 to 1.5). Significant visual loss (≥ 2 lines loss of BCVA) was not observed. Post-operative recovery of BCVA in this group is demonstrated in Figure 3.

Post-operative Complications

All complications were minor and successfully managed at the follow-up examinations. No complications with lasting effect on visual results were encountered. In the 90 µm group, minor flap-related complications were observed at follow-up examinations: micro-striae in four eyes (3.9 %), very minor interface haze in two eyes (1.9 %), slightly irregular flap border in two eyes (1.9 %) and debris under the flap in two eyes (1.9 %). In the 80 µm group a slightly irregular flap border was noted in one eye (3.7 %). Two eyes showed a slight epithelial disturbance (7.4 %). There was a small subconjunctival bleeding in two eyes (7.4 %). In three eyes (11.1 %) debris under the flap occurred. In one case (3.7 %) there was interface haze.

Discussion

Over the past decade various investigators have reported the use of femtosecond lasers for the creation of corneal flaps.¹¹⁻¹⁶ To our knowledge, this is the first report of a case series using the Ziemer LDV femtosecond laser for creation of ultra-thin corneal flaps. The term 'thin-flap LASIK' has

been used to describe LASIK procedures performed using high-energy femtosecond lasers to create flap thickness of 100–110 μm .^{22–28} However, we suggest the term ultra-thin-LASIK should describe the general principle of flap creation with a femtosecond laser using an 80 or 90 μm InterShield spacer followed by excimer laser ablation, as opposed to the use of a mechanical microkeratome.

The FEMTO LDV femtosecond laser with its unique characteristics lends itself to creating ultra-thin flaps due to the high precision and repeatability of dissections. In particular, the high numerical aperture of its optics ensures excellent focus of laser energy in the cutting plane, minimising thermal damage in tissue above or below the plane.²⁹ This allows cutting close to Bowman's membrane without the risk of damage to it or to the epithelium.

Average epithelium thickness in healthy eyes is $53.8 \pm 4.6 \mu\text{m}$ and Bowman's membrane thickness is 8 to 10 μm .³⁰ The 'danger zone' therefore is approximately 68 μm . Approximately one in 40 epithelia can be >2 SDs thicker than average, which extends the danger zone to approximately 73 μm . As the results of this study demonstrate, the achieved precision of thickness for 80 μm flaps is $\pm 6.80 \mu\text{m}$ (SD) and two of the flaps in the 80 μm group were only 69 or 70 μm thick; for the 90 μm flaps the achieved thickness precision is $\pm 8.26 \mu\text{m}$ (SD).

In this study, the mean flap thickness in the 80 μm group was 81.91 μm . Actual epithelium thickness in individual eyes is not known. It must be assumed that these dissections were placed approximately 19 μm

underneath the Bowman's membrane on average. Considering the SDs of epithelium thickness and of flap thickness, some flaps may have 10 μm or less of stroma under the Bowman's membrane. Some of the complications reported in this study are likely to be a consequence of marginal flap thickness. The small number of complications reported can be ascribed to the femtosecond laser achieving excellent focus at consistent depth.

Since the Ziemer LDV femtosecond laser offers a high degree of precision in the creation of 90 μm flaps for LASIK, using this device for creating 90 μm flaps, can be considered a safe and effective procedure for LASIK patients with thin corneas and/or higher ametropia. While some of the attempted 80 μm cuts performed in this study did produce the expected result, some complications occurred. However, they did not result in any significant visual loss. Despite this the authors of this study consider the relatively high rate of complications with 80 μm flaps is too great a risk of standard femto-LASIK procedures, particularly when epithelium thickness and location of Bowman's membrane are not known. The clinical trials with the 80 μm InterShield spacer were therefore discontinued, as they appeared to provide no real advantage with a slightly increased risk of minor complications. For this reason, the present study contains fewer 80 μm flap cases.

In summary, this study demonstrates that for the Ziemer LDV femtosecond laser, ultra-thin flap LASIK at 90 μm is a viable procedure for cases such as those with thinner corneas and or higher amounts of tissue ablation in higher myopes in whom preserving the highest possible amount of residual stroma under the flap is indicated. ■

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