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Measurement of the Intraocular Pressure Elevation During Laser-Assisted In Situ Keratomileusis Flap Creation Using a Femtosecond Laser Platform

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Received: April 22, 2020
Accepted: January 25, 2021
Published: March 10, 2021

Keywords: femtosecond laser (FS); intraocular pressure (IOP); laser assisted in situ keratomileusis (LASIK)

Citation: Lauzirika G, Garcia-Gonzalez M, Bolivar G, Hernández-Verdejo JL, Blázquez Sánchez V, Gros-Otero J, Teus MA. Measurement of the intraocular pressure elevation during laser-assisted in situ keratomileusis flap creation using a femtosecond laser platform. Trans Vis Sci Tech. 2021;10(3):9, https://doi.org/10.1167/tvst.10.3.9

Purpose: The purpose of this study was to measure the intraocular pressure (IOP) elevation during laser assisted in situ keratomileusis (LASIK) flap creation using the WaveLight FS200 femtosecond (FS) laser platform.

Methods: We conducted an ex vivo experimental study in an animal model. The WaveLight FS200 FS laser platform was used to perform the corneal LASIK flap in freshly enucleated porcine eyes. We measured the changes in IOP from the application of the suction ring (suctioning phase) through the creation of the lamellar corneal flap (cutting phase). The IOP was recorded using a manometric technique with direct cannulation to the anterior chamber.

Results: Nine freshly enucleated porcine eyes were included in the study. The mean baseline IOP before the procedure was 20.33 $\pm$ 5.9 mm Hg. The mean IOP increase over baseline IOP was 32.33 $\pm$ 11.3 mm Hg at the suctioning phase, and 38.22 $\pm$ 11.3 mm Hg at the cutting phase. The total surgical time needed to complete the procedure was 29.5 $\pm$ 4.4 seconds.

Conclusions: The WaveLight FS200 FS laser platform produces a low to moderate increase in IOP during LASIK flap creation.

Translational Relevance: The WaveLight FS200 is a safe FS laser platform because it induces a low to moderate IOP increase during LASIK flap creation.

Introduction

Laser assisted in situ keratomileusis (LASIK) is considered one of the techniques of choice to correct ametropias, due to its fast visual rehabilitation and its low incidence of complications.[1] The creation of a LASIK flap can be performed by using a mechanical microkeratome (MM) or a femtosecond (FS) laser.

Although several FS laser platforms have been specifically developed for LASIK flap creation and other corneal procedures, it is noteworthy that the majority of published studies report the visual outcomes and the corneal flap features when using the Intralase (Abbott Medical Optics, Inc., Santa Ana, CA, USA),[2–6] which was the first clinical FS laser approved by the US Food and Drug Administration for creating lamellar corneal flaps. The IntraLase uses

a specific system composed by a suction ring (coupled to a manual syringe) and a flat patient interface (FI) that induces an applanation of the cornea to allow a perfect cut, parallel to the corneal surface.

The Wavelight FS200 (Alcon Laboratories Inc., Fort Worth, TX, USA) is another FS laser currently available to perform corneal procedures such as LASIK flaps. The WaveLight FS200 shares with the IntraLase the fact that both platforms use an FI that induces an applanation of the cornea, but compared to the IntraLase that uses (as a pump) a manual syringe coupled to the suction ring, the WaveLight FS200 uses a suction ring with an automatic suction pump.

Theoretically, an FI requires a higher level of suction and induces a greater elevation of the intraocular pressure (IOP) during the LASIK flap creation. In fact, our group has previously reported using a validated experimental model, that IOP reached approximately 90 mm Hg during the suctioning phase and 120 mm Hg during the intrastromal laser application of the IntraLase FS laser.[7] However, to our knowledge, the IOP increase induced by the WaveLight FS200 FS laser during LASIK flap creation is currently unknown.

For this reason, and taking into account that the sudden intra-operative increase in IOP during LASIK can be associated with several potential vision-threatening complications,[8–11] we decided to measure the real-time changes in IOP during LASIK flap creation using the WaveLight FS200 FS platform.

Methods

In this ex vivo experimental study in an animal model, we prospectively evaluated the changes in IOP from the application of the suction ring (suctioning phase) through the performance of the corneal LASIK flap (cutting phase) when using the WaveLight FS200 FS laser device.

The study was performed in accordance with the ARVO Statement for the use of animals in Ophthalmic and Vision Research. Freshly enucleated porcine eyes were used to measure the IOP during the whole surgical time. All eyes were free of corneal damage when inspected by slit-lamp microscopy. Before starting with the measurement, all eyes were inflated with a 5% glycosylated solution through the optic nerve (a method previously described by Kasetsuwan et al.)[12] to obtain an IOP between 10 and 30 mm Hg, that was checked by Perkins applanation tonometry. Then, the eyes were placed on a specific holder with sufficient support to withstand the surgical procedure (Fig. 1).

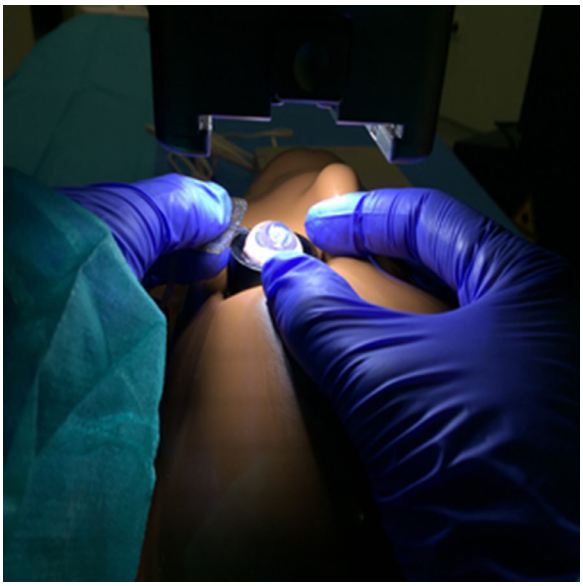

Figure 1. Placement of the eye on a specific holder with sufficient support to withstand the experiment.

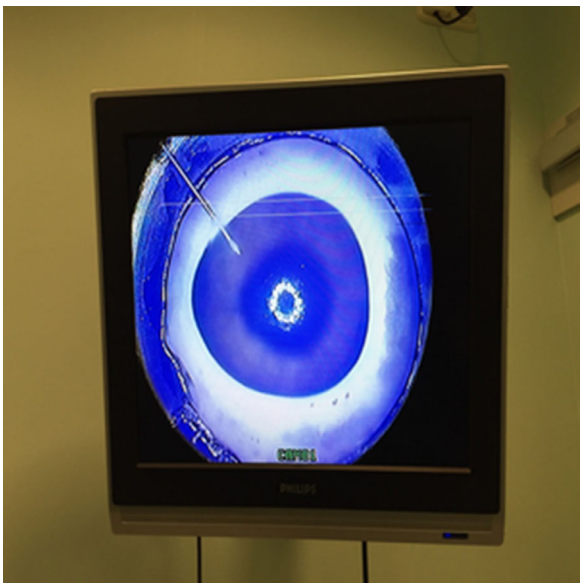

Figure 2. Validated method in which a transducer connected to the anterior chamber is used to measure the real-time IOP during the LASIK flap creation.

Real-time IOP can be reliably measured during LASIK, using a transducer connected to the anterior chamber, as previously described by our team, so we decided to use the same validated method (Fig. 2).[7,13] The IOP was measured in the anterior chamber using a 27-gauge winged infusion (Set REF 387412 ValuSet; BD Biosciences, Hull, UK) that was inserted through the limbus in such a way that the suction ring could be applied over the sclera without touching the needle. IOP measurements were obtained with a reusable blood pressure transducer (MLT0380

Reusable BP Transducer, Power Laboratory; AD Instruments, Racine, WI, USA). The transducer is an external sensor for coupling to vascular pressure (in our experiment, the IOP in the anterior chamber) via a liquid-filled catheter. The transducer was prepared according to the manufacturer's instructions to ensure an airtight seal and all air was discharged from the system. The recorder was set to 0 to initialize the transducer. Before starting the procedure, the transducer was checked to verify that the pressure would be registered correctly. For calibration, a calibrated mercury manometer was connected to the transducer and checked that the pressure of the mercury manometer and the pressure of the screen connected to the transducer were similar.

All the surgical procedures were performed on the same day by the same experienced surgeon (M.G.-G.), and following the same protocol.

The Wavelight FS200 laser (software version 1.101 greensp2) used the following parameters: a raster pattern using a 0.80 µJ bed energy level, a spot size of 5 µm, a spot and line separation of 8 µm, an attempted flap thickness of 120 µm, and a flap diameter of 9.0 mm.

During LASIK flap creation with the Wavelight FS200, there is a phase of suction-globe fixation, when the suction ring is applied and the suction is activated, and afterward the corneal applanation takes place when the patient interface is docked into the suction ring. Finally, the photodisruption process starts and the corneal flap is obtained.

During the procedure, the IOP was recorded continuously with the amplifier (ML110 Bridge Amplifier; AD Instruments, Castle Hill, Australia) connected to the barometric transducer, from the time of the application of the suction ring (suctioning phase) through the end of the creation of the corneal LASIK flap (cutting phase). The IOP was also measured before and after the suction ring was placed, using a Perkings handheld tonometer (Clement Clarke, Essex, UK). The IOP level after the procedure had to be at least 6 mm Hg, to rule out any substantial fluid leakage from the eye during the experiment.

Results

Nine freshly enucleated porcine eyes were included in the study. The mean baseline IOP before the surgical procedure was 20.33 ± 5.9 mm Hg. The mean IOP increase (over baseline IOP) during the suctioning phase was 32.33 ± 11.3 mm Hg. The mean IOP increase during the cutting phase was 38.22 ± 11.3 mm Hg.

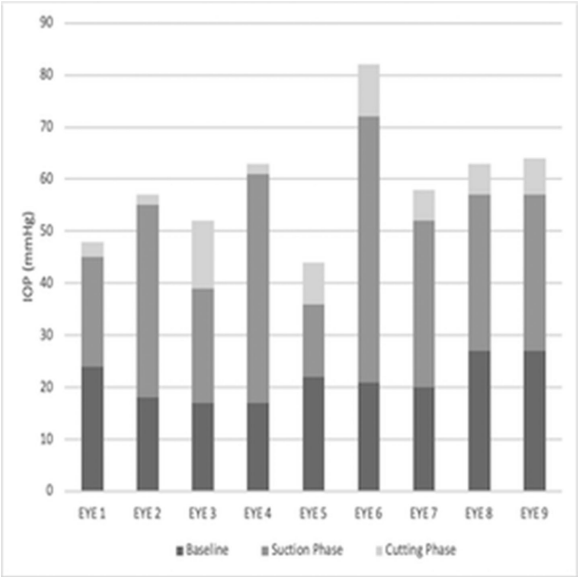

Figure 3. IOP value over the baseline obtained in each eye at the suctioning and the cutting phases, respectively.

The IOP values reached during the suctioning and the cutting phases of each eye in shown in Figure 3 and in Table 1.

The total time needed to complete the whole procedure was 29.5 ± 4.4 seconds (i.e. a mean time of 14.2 ± 3 seconds and 15.3 ± 2.5 seconds were required for performing the suctioning and the cutting phases, respectively).

Discussion

In this ex vivo experimental study with porcine eyes, we measured the real-time IOP rise when using the Wavelight FS200 laser device for obtaining a LASIK corneal flap. Based on our results, the Wavelight FS200 FS laser induces a low to moderate mean increase in IOP of 32.33 ± 11.3 mm Hg and 38.22 ± 11.3 mm Hg over baseline during the suctioning phase and the cutting phases, respectively.

To our knowledge, this is the first study that evaluates the real-time IOP increase when the Wavelight FS200 laser device is used. The WaveLight FS200 shares with the IntraLase family the fact that both FS laser platforms use a flat interface for corneal applanation but they differ in the suction mechanism: the FS200 uses a suction ring with an automatic suction pump, whereas the IntraLase uses a manual syringe as a pump, coupled to the suction ring. Interestingly, using the same validated methodology for measuring IOP, as in our study, both the IntraLase 60-kHz[7] and the iFS 150-kHz[14] – the latest generation of the IntraLase

Table 1. IOP Increase in Each Eye During the Suction and the Cutting Phases, and the Time Needed in Each Surgical Step

	Baseline	Δ IOP[a] Suction Phase, mm Hg	Suction Time, s	Δ IOP[a] Cutting Phase, mm Hg	Cutting Time, s	Total Surgical Time
Eye 1	24	21	20	24	20	40
Eye 2	18	37	10	39	16	26
Eye 3	17	22	13	35	17	30
Eye 4	17	44	16	46	14	30
Eye 5	22	14	16	22	16	32
Eye 6	21	51	11	61	16	27
Eye 7	20	32	13	38	14	27
Eye 8	27	30	15	36	11	26
Eye 9	27	30	14	37	14	28

[a] **Δ** IOP, IOP increase over baseline.

family – induce an increase in IOP of nearly 80 to 90 mm Hg during the suctioning phase and 110 to 120 mm Hg during the cutting phase, values that are significantly higher compared to those obtained with the FS200 in the current study.

Similar to the IntraLase family, Vetter et al.[15] found that the Femto LDV (Ziemer Ophthalmic Systems AG) induce higher suction IOP levels during the corneal flap cut (up to 184 ± 28 mm Hg) in porcine eyes. Although the method they used for cannulation differs from ours, it seems that the Femto LDV, which also uses an FI but a single built-in suction pump,[16] induces a significantly higher increase in IOP compared to the FS200.

On the other hand, two other FS laser platforms, the VisuMax (Carl Zeiss Meditec AG) and the Femtec (Technolas Perfect Vision), have been designed to perform only corneal procedures and they both use a curved interface (CI). Theoretically, the FS laser devices that use a CI should induce lower IOP rises as compared to those that use an FI.[17–19] As expected, Vetter et al.[15] found that the VisuMax induced the lowest mean IOP (65 ± 20 mm Hg) but, surprisingly, they found that the mean IOP was remarkably higher with the Femtec (205 ± 32 mm Hg) compared to the IntraLase (135 ± 16 mm Hg) and the Femto LDV (184 ± 28 mm Hg). Interestingly, similar conclusions were obtained by Strohmaier et al.,[20] although using a different method for IOP measurement.

Moreover, new FS laser platforms have been developed to perform, not only corneal procedures such as LASIK flaps, but also FS laser-assisted cataract surgery (FLACS) with the same device[2]: the FEMTO LDV Z8 (Ziemer Ophthalmic System AG, Port, Switzerland), the Victus (Bausch & Lomb Incorporated, Rochester, NY, USA), and the LenSx (Alcon LenSx Inc., Aliso Viejo, CA, USA). The Victus uses a CI and a suction ring coupled to an automatic suction pump, whereas the LenSx uses a CI but an automatic suction pump directly coupled to the patient interface (so the suction, globe fixation, and corneal applanation happen simultaneously).

Our group has previously evaluated the IOP rises when using the Victus and the LenSx for LASIK flap creation[14] and the Catalys for FLACS,[21] using the same methodology as in the current study. As theoretically expected, due to its CI, the LenSx induced a small IOP increase of only 20 ± 5.3 mm Hg during the cutting phase. In contrast, the Victus induced a small IOP increase of 20.3 ± 6.6 mm Hg during the suctioning phase (similar to the LenSx), but despite having a CI, during the cutting phase, the Victus induced a significantly higher IOP increase than the LenSx (96.4 ± 16.8 versus 20 ± 5.3 mm Hg, respectively; Table 2). Therefore, and compared with the previous published reports, it seems that the FS200 (FI) induces a moderate increase in IOP during LASIK flap creation, which is significantly lower compared to the iFS (FI) and the Victus (CI) and slightly higher compared to the LenSx (CI).

Therefore, based on our results, it seems that the type of corneal interface (flat versus curved) is not the only factor that influences in the IOP elevation during the procedure. We do believe that other factors, such as the size of the applanation device, the level of vacuum achieved by the suction pump, or the amount of pressure induced by the patient interface over the cornea, must also contribute to the final IOP increase reached by each FS platform.

Another important factor to determine is the total time needed to complete the procedure. Interestingly, those platforms that use an independent suction ring spend longer total surgical times (25.10 ± 4.3 seconds with the iFS, 29.5 ± 4.4 seconds with the FS200 – the current study – and 33.40 ± 3.1 seconds with

Table 2. Intraocular Pressure Increase and Optical Density Values of the FS200 Compared With Other Femtosecond Laser Platforms

	FS200, Current Study[23]	Intralase 60KHz[7]	iFS 150KHz[14,22]	LenSx[14,22]	Victus[14]
Baseline IOP,[a] mm Hg	20.33 ± 5.9	11.5 ± 3.43	21.14 ± 3.44	21.14 ± 5.15	20.71 ± 7.89
Δ Suction phase,[b] mm Hg	32.33 ± 11.3	89.24 ± 24.26	78.14 ± 23.62	No suction ring	20.28 ± 6.65
Δ Cutting phase, mm Hg	38.22 ± 11.3	119.33 ± 15.88	108.14 ± 16.97	20 ± 5.29	96.42 ± 16.83
Total surgical time, s	29.55 ± 4.4	92.85 ± 13.49	25.10 4.26	17.21 ± 0.68	33.40 ± 3.1
Flap OD, GSU	149 ± 28	Not evaluated	134.55 ± 6.5	158.9 ± 18.6	Not evaluated

It is noteworthy that all the studies included in this table used the same experimental methodology as in the current study.
Δ Cutting Phase, IOP increase over baseline at cutting phase; Δ Suction Phase; IOP increase over baseline at suction phase; GSU, gray scale unit; IOP, intraocular pressure; OD, optical density.

the Victus),[14] whereas the LenSx showed not only the lowest IOP rise during the cutting phase but also the shortest total surgical time (17.21 ± 0.7 seconds[14]; see Table 2).

Finally, a relevant issue that needs to be better analyzed is if the differences in the characteristics of each FS laser platform (FI versus CI, low IOP versus high IOP) are clinically relevant in terms of postoperative refractive outcomes and flap features. Interestingly, our group has recently reported that FS lasers that use a FI and that induce high IOP (such as the IntraLase iFS-150kHz)[22] provide thinner, more predictable, and more homogeneous flaps than FS lasers that use FI but working under low IOP (FS200),[23] FS lasers working with CI and low IOP (LenSx)[22] and those working with a CI and high IOP (Victus).[24] We do believe that this is an important finding because we have detected a clinically significant correlation between flap thickness homogeneity and postoperative visual outcomes (i.e. more homogeneous flaps provide better final visual and refractive outcomes and less induction of higher order aberrations).[22–25]

In addition, we also found a clear relationship between the early postoperative flap optical density (OD) (that is an indicator of corneal transparency) and the level of IOP reached during LASIK flap creation. Thus, OD was initially lower in flaps obtained with platforms that induce a high IOP increase[7,14] (i.e. flap OD was 134.5 ± 26.9 gray scale units [GSUs with the IntraLase iFS-150kHz at 1 day postoperatively)[22] compared to those platforms that induce a low IOP increase,[14] such as the LenSx (158.9 ± 18.6 GSU)[22] and FS200 (149.6 ± 28.4 GSU).[23] Fortunately, this transient corneal edema found in the LenSx and the FS200 eyes tend to decrease over time, without affecting the final visual outcomes and the corneal transparency at 3 months postoperatively.[22,23]

Theoretically, high levels of IOP during FS-LASIK might compromise the retinal nerve fiber layer (RNFL); however, we previously reported that the IntraLase (that induces a high IOP increase) did not cause RNFL thinning[26] and, thus, this potential complication might not be expected when using the FS200 (that induces a low to moderate IOP increase).

For all these reasons, it is clear that more studies are needed to establish the "ideal characteristics" that might have an FS laser platform in order to obtain a "perfect" LASIK flap in terms of flap thickness accuracy, flap thickness homogeneity, and optical transparency.

We are conscious that one limitation of the current study is that it has been performed in enucleated porcine eyes. Therefore, it might be that the results we obtained may not identical to the behavior of living human eyes.

In conclusion, our preliminary results suggest that the WaveLight FS200 FS laser platform induce a low-moderate IOP increase during LASIK flap creation. More studies are clearly needed to determine the ideal level of IOP that an FS laser device might reach during LASIK flap creation, searching for a balance between LASIK flap quality and ocular safety.

Acknowledgments

The authors thank all those administrative and technicians who provide the necessary to perform this study.

This study has not been funded by any private or public institution. None of the authors has a financial or proprietary interest in the material or method mentioned.

Disclosure: **G. Lauzirika,** (N); **M. Garcia-Gonzalez,** (N); **G. Bolivar,** (N); **J.L. Hernández-Verdejo,** (N); **V. Blázquez Sánchez,** (N); **J. Gros-Otero,** (N); **M.A. Teus,**

J&J Vision (F, S), Alcon (F, C, S), Allergan (F, C), Bausch&Lomb (F), Novartis (F, S), Tear Lab (F, S)

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