

Flap results

Microkeratome creates high-quality, predictable flaps and smooth beds, studies show

Surgeons describe performance of Zyoptix XP device compared with other flap-creation technology

By Cheryl Guttman

Reviewed by Hung Ming Lee, MD and Robert K. Maloney, MD

Studies evaluating the new Zyoptix XP microkeratome (Bausch & Lomb) indicate that it performs safely and reliably to cut LASIK flaps of a reproducible thickness with a standard deviation that matches or exceeds results reported for the femtosecond laser (IntraLase).

"There will always be some variation in flap thickness with any microkeratome because of differences in tissue response to flap creation, but the goal is for that value to be as low as possible," said Robert K. Maloney, MD, director, Maloney Vision Institute, Los Angeles. "Experience with the Zyoptix XP indicates that this new-generation microkeratome has eliminated the surgeon-dependent factor so that any user can expect low variation in flap thickness."

At the recent American Society of Cataract and Refractive Surgery annual meeting, Dr. Maloney presented the results of a retrospective study analyzing flap thickness and variability achieved with the Zyoptix XP in a series of 50 patients who underwent bilateral flap creation using the same blade for both eyes. The microkeratome was equipped with the 120- μ m plate, and the results showed it created first-eye flaps of an average thickness that was very close to the nominal thickness with a very low variability. The mean \pm SD for flap thickness was $123 \pm 14.8 \mu\text{m}$. Flaps in the second eye were thinner on average, but also close to the nominal thickness and with a reasonably low standard deviation ($112 \pm 18 \mu\text{m}$).

"The low flap thickness variability in this study is comparable to the range of 12 to 18.5 μm that has been reported in the literature

for the femtosecond laser keratome, and the finding of thinner flaps in the second eye is also consistent with previous studies using other mechanical microkeratomers," said Dr. Maloney, who is also clinical professor of ophthalmology, Jules Stein Eye Institute, University of California at Los Angeles.

Compared with laser technology

Hung Ming Lee, MD, of the Refractive Surgery of the Eye Institute, Tan Tock Seng Hospital, Singapore, directly compared the Zyoptix XP microkeratome with the 15-kHz femtosecond laser in a prospective, bilateral study including 50 patients with comparable spherical equivalent (SE) and best-corrected visual acuity (BCVA) levels in fellow eyes. Intended parameters were 120 μm for thickness and 8.5 mm for diameter using both flap creation devices. Dr. Lee was operating with the Zyoptix XP as a novice while he was an experienced user of the femtosecond laser.

Based on measurements made with both ultrasound pachymetry and online optical coherence pachymetry (OCP), the analyses showed the Zyoptix XP was more accurate than the femtosecond laser in achieving the intended flap thickness. The Zyoptix XP produced an average flap that was thinner than intended, and the average femtosecond laser flap was thicker than its target. Using ultrasound pachymetry, mean flap thickness was 116 μm for the Zyoptix XP and 152 μm for the femtosecond laser flaps. Measurements made with OCP were approximately 7% less due to its use of a different refractive index value, but showed a similar relative pattern with a mean flap thickness in the Zyoptix XP group of 109 μm that was thinner than intended and closer to its target than the mean value of 137 μm in the femtosecond laser group.

'Surgeons who use [this device] can expect to achieve the same level of precision, predictability, and outcomes that have been ascribed to the latest-generation laser flap-creation technology.'

Hung Ming Lee, MD

Variability in flap thickness was similar for the two techniques. Standard deviation (SD) for ultrasound pachymetry-measured flap thickness was 16.1 μm for the Zyoptix XP and 16.2 μm for the femtosecond laser. Using OCP, the corresponding SD values were 14.4 μm and 15.9 μm , respectively.

"These findings strongly suggest that surgeons who use the Zyoptix XP can expect to achieve the same level of precision, predictability, and outcomes that have been as-

Take-Home Message

Studies evaluating flap creation with the Zyoptix XP microkeratome (Bausch & Lomb) find it cuts flaps close to the nominal thickness and with a very low standard deviation that matches or exceeds that associated with the femtosecond laser (IntraLase). Investigators report their outcomes with the Zyoptix XP and discuss its design features that account for its safe and reliable performance.



Dr. Lee



Dr. Maloney

cribed to the latest-generation laser flap-creation technology," Dr. Lee said.

Analyses of outcomes at 1 month after surgery showed that uncorrected visual acuity (UCVA), high- and low-contrast BCVA, and predictability outcomes were similarly excellent in both groups. UCVA averaged almost 20/16 regardless of the device used for flap creation. Almost 92% of eyes treated with the Zyoptix XP and about 87% of the eyes treated with the femtosecond laser were within 0.5 D of their refractive target.

Smooth beds

Dr. Lee's study also included surgeon ratings of microkeratome performance based on several parameters. Using a grading scale of 0 to 100, the ratings were high for both microkeratomes in all assessments, but the mean score for ratings of stromal bed quality was significantly higher in the Zyoptix XP group compared with that associated with the femtosecond laser. However, the opportunity to reduce spot separation size using the 60-kHz femtosecond laser results in creation of a smoother corneal bed using that instrument compared with the 15-kHz laser used in this study, Dr. Lee noted.

Dr. Maloney has also been impressed with the high quality of both the stromal beds and flaps achieved using the Zyoptix XP.

"Use of the Hansatome was sometimes associated with chatter marks in the stromal bed that I suspect represent subclinical buttonholes in an area where the blade rose slightly and then dove back down," Dr. Maloney said. "In my experience using the Zyoptix XP, the beds have been remarkably smooth, and part and parcel with that is the fact that I have never encountered a single buttonhole with Zyoptix XP flap creation."

Dr. Maloney attributed that finding to the design of the Zyoptix XP.

"The XP is a redesigned microkeratome and appears to mate with the eye in such a way that the suction achieved is very reliable. That feature might explain the freedom from buttonholes as well as the consistently low standard deviation in flap thickness between



The Zyoptix XP microkeratome.

'We have never had to cancel cases because of operational problems with [the device]!

Robert K. Maloney, MD

surgeons," he added.

An integrated motor/gear box and improved surgical blade tolerance also contribute to the performance of the Zyoptix XP in producing a smooth stromal bed and reproducible flap thickness, Dr. Maloney said.

The Zyoptix XP microkeratome was designed for safety and efficiency. The gears are fully enclosed so that there is no chance of catching the lids or lashes, and the instrument can be switched seamlessly from eye to eye simply by flipping the OD/OS selector switch. With a new raised drive assembly, the Zyoptix XP allows for 360° variable hinge placement and so can create nasal, superior, or oblique hinges. In addition, the parts are all interchangeable so that part replacement can be achieved without shipping back the entire microkeratome.

"We have never had to cancel cases because of operational problems with it," Dr. Maloney said.

In further analyzing the data collected in his study, Dr. Maloney found that the pre-flap central corneal pachymetry measured intraoperatively was significantly greater in

the first eye versus the second eye, 550 versus 545 μm . He noted, however, that when the two eyes were measured preoperatively in the clinic, there was no significant difference between the mean values for the first and second eyes.

"It appears from these results that about half of the difference in flap thickness between eyes can be accounted for by some dehydration of the second eye that occurs when operating on the first. This study, however, could not answer whether variability in the dehydration or some blade-related factor accounts for the slightly larger variability in flap thickness in the second eye," Dr. Maloney said.

"The practical significance of these findings is that if your preoperative calculations of residual bed thickness indicate one eye is borderline and the other is adequate, operate on the adequate eye first, determine the flap thickness, and then you can estimate that the second eye flap will be on average 11 μm thinner," he added.

Flap thickness in both eyes

In another analysis, Dr. Maloney investigated the relationship between flap thickness in the first and second eyes and found the two values were strongly correlated.

"To my knowledge, this phenomenon has not been reported before, and it has practical significance. If the calculated residual bed thickness is borderline in one eye and adequate in the other, once again, operate on the adequate eye first. If the flap turns out to be thinner than the nominal value, then you might proceed with some greater assurance in the second eye. However, if the flap turns out to be thick, it might pay to be a little more cautious about proceeding with the second-eye surgery," he said. \square

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Dr. Lee has no financial interest in the Zyoptix XP microkeratome. He is not a consultant to Bausch & Lomb or IntraLase. Dr. Maloney is a consultant to Bausch & Lomb.