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SBK with the XP Microkeratome

An evolutionary step for laser refractive surgery?

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For many years, the routine LASIK procedure for treating myopia or hyperopia included creation of a stromal flap, at least 140 µm to 160 µm in depth and approximately 8.5 mm to 9.5 mm in width. Flap thickness was not often a significant concern as long as a residual stromal bed of 250 µm was preserved. In fact, many suggested that surgeons should avoid very thin flaps as there was an unproven notion that such flaps were more likely to wrinkle and would be harder to handle. Recent information on the advantages of thinner, sub-Bowman's flaps has led me to re-examine the traditional approach to flaps. In this article, I will discuss the rationale, technique and personal results on sub-Bowman's keratomileusis (SBK) performed with a 90- to 110-µm flap created with the Zyoptix XP microkeratome (Bausch & Lomb, Rochester, N.Y.).

Ideal Flap Thickness

Currently, refractive surgeons are debating the relative merits of LASIK and surface ablation in performing laser refractive surgery. Proponents of LASIK cite pain, haze and longer recovery following surface excimer laser procedures as tipping the advantage to LASIK, while backers of PRK point out biomechanical weakening of the cornea and dry eye following creation of standard LASIK flaps.

More ominously, proponents of surface ablation cite examples of unexpected ectasia following LASIK that presumably would have been avoided had surface ablation been performed. Steven Slade, M.D., and Daniel Durrie, M.D., have introduced a new form of laser refractive surgery that combines the best of LASIK and PRK: a technique they have called sub-Bowman's keratomileusis or SBK.[1] This technique is defined by 3 characteristics: 1) flap thickness of 90 to 110 µm 2) a planar flap architecture and 3) customized flap diameter that minimizes the diameter to coincide with the edge of the laser ablation.

John Marshall, Ph.D., professor of ophthalmology at King's College in London, has postulated that SBK may combine the best features of PRK and LASIK, providing the protection of biomechanical stability with the quick recovery and lack of haze seen with lamellar surgery.[2,3] Marshall and colleagues' research using X-ray diffraction demonstrated that the greatest strength of the cornea lies within the first 150-µm depth of the stroma. In this anterior region, the corneal lamellae (composed of collagen fibrils) are small, tightly interwoven and packed the tightest. It is difficult to pull them apart because of the great biomechanical strength there. The researchers also demonstrated variations in strength across different areas of the cornea. In the central part, collagen fibrils cross at right angles (90°), a mechanically weak arrangement. In contrast, at the periphery, the fibrils cross at about 120°, which creates strength.

This finding means that the traditional LASIK flap biomechanically weakens the cornea for two related reasons: it separates out the the mechanical protection of the strong anterior coat and does so in the area where the corneal lamellae are at their weakest due to the angle of fibril crossing. Marshall and colleagues point out that that a more superficial corneal flap of approximately 100 µm provides excellent biomechanical stability and strength to the residual cornea. They state that stability of such a cornea may exceed that of a post-PRK cornea.[3]

Ideal Flap Architecture

In addition to 90-µm to 110-µm flap thickness defined by Drs. Slade and Durrie, a successful sub-Bowman's keratomileusis procedure includes a planar flap — one with consistent thickness across the entire surface of the cornea. If a flap is deeper in the periphery and thinner in the center, the stromal bed may be uneven and visual results may be affected. Research conducted in Munich, Germany using Visante high-resolution, non-contact OCT (Carl Zeiss Meditec, Dublin, Calif.) showed that flaps created with the Bausch & Lomb Zyoptix XP microkeratome provided excellent planar architecture and exhibited no marked differences in uniformity of thickness from flaps created with the IntraLase FS30 femtosecond laser (Advanced Medical Optics, Santa Ana, Calif.)[4] (**Figure**).

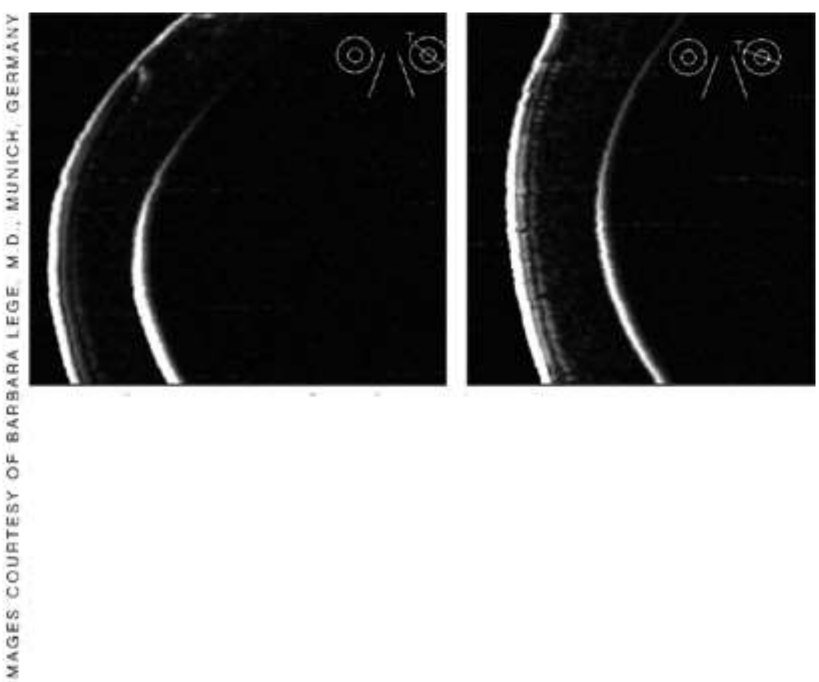

Figure. Flap made with Zyoptix XP microkeratome (left) and flap made with the Intralase FS30 (right) are similar. Images taken with Visante anterior segment, high-resolution, non-contact OCT.

Ideal Flap Diameter

In addition to a thin flap and planar contour, Drs. Durrie and Slade suggest making a minimal flap diameter, one most closely approximating the edge of the laser ablation. Although I agree regarding the value of thinness and planar architecture, I am skeptical on the need for the smallest possible diameter flap.

Dr. Marshall's data suggests that flap diameter is completely irrelevant because a flap of approximately 100-μm thickness has no significant weakening of biomechanical stability due to the strength of the next deeper layer of collagen fibrils.[3] In addition, as demonstrated by Alpins and associate, PRK has such a minimal impact on corneal strength that it can be safely used on stable keratoconus patients.[5] Thus, if the flap itself contributes an insignificant degree of weakening, it would not matter if the flap diameter was 8 mm, or 10 mm.

Given the changes that Marshall reported in the angle of collagen fibrils crossing from a weaker 90° centrally to a stronger 120° peripherally, along with the cornea becoming increasingly thicker peripherally, the peripheral cornea is actually stronger than the central cornea. Thus, any biomechanical impact of a flap decreases peripherally in progressive fashion. Finally, with the laser ablation producing the greatest corneal thinning in the approximately central 6 mm, depending on the type of laser, any peripheral flap will lie on stronger, unablated tissue, making flap diameter outside the ablation area less relevant to the final residual corneal thickness.

Advantage of a Larger-Diameter Flap

A slightly larger diameter flap offers the option of lifting the flap at a later date to place a larger-diameter laser ablation, should technology change or a future, larger-diameter ablation, such as a hyperopic ablation, be required.

With femtosecond-created flaps being harder to lift in many cases, creating a smaller-diameter new flap inside the previous flap boundaries has two negative effects. First, it forces a new, deeper flap that would no longer be SBK in its depth. Such a deep flap might raise concerns over remaining stromal depth for corneal stability in an enhancement patient — the very patient whose cornea might be demonstrating an above average degree of biomechanical weakness.[6] It might also make it difficult to place the larger-diameter new ablation in the future because a flap of minimal diameter in the original surgery would have to be even narrower for the second surgery.

In my view, a larger-diameter flap is, theoretically, better protection against mild degrees of epithelial ingrowth because the epithelium would have a greater distance to travel before it reached a critical level of encroachment.

Flap Size in an ALK Treatment Model

Another theoretical, but yet unproven, reason for larger-diameter flaps is the hypothetical concern that a smaller-diameter flap might actually concentrate forces over a smaller area, increasing the potential for ectasia in predisposed patients.

Supporting this assumption is the example of hyperopic anterior lamellar keratoplasty (ALK). In a model for this lamellar treatment for hyperopia, an intentionally thick flap of approximately 70% of corneal depth was made to create "controlled ectasia" to induce forward bowing of the cornea. Flap thickness was kept constant over the range of hyperopic correction and flap diameter was the only variable used to control the amount of intentionally induced forward bowing.

In an effort to force all of the ectatic forces over a smaller surface area and increase the bulging of the ectasia, a smaller flap was used for higher degrees of hyperopia. A larger flap of the same depth was used to create less ectasia for lower degrees of hyperopia. Smaller-diameter flaps were used to accentuate ectasia in this model. Similarly, in a predisposed patient with a biomechanically weak cornea, a larger flap might provide a protective effect. Clearly this is theoretical, but does call into question the intuitively appealing concept that the smallest diameter flap is, a priori, better.

SBK with the Zyoptix XP Microkeratome

I have developed a technique with the Zyoptix XP microkeratome to precisely and reproducibly perform the SBK procedure.

Starting with placement of the XP microkeratome on the eye, a surgeon has a choice of a 19-mm or 20-mm suction ring, but starting with the 20-mm ring is the product recommendation. The 19-mm ring has traditionally been recommended for tight orbits in which placement of a 20-mm would be difficult. However, the suction on the 19-mm ring is not as strong as with the 20-mm, and we thought there was a possibility that decreased suction might affect flap thickness. We performed a study on the patients' first eyes using the 9.5-mm diameter 19-mm ring, in conjunction with the 120-µm labeled microkeratome head to answer this question and help us delineate our parameters. Our second step was to study the same patients' consecutive, second eyes using the 9.5 mm diameter 20-mm ring in conjunction with the 120-um head.

The 20-mm ring with a 120-µm Zyoptix XP head had been shown to accurately produce a 120-µm flap.7 Thus, we expected that a 19-mm ring and the 120-µm head would produce a thinner flap. And, just as we thought, and as the data in the **Table** shows, we were able to consistently get flaps very close to 100-µm with that combination.

The second part of the procedure to develop was hand position and technique. To prevent unpredictable variability in suction, we did not want to introduce any new forces, so we attempted to avoid any downward or upward pressure when the XP microkeratome was on the eye. With that in mind, we developed a technique that was neutral to the z-axis (the up-down axis), which allowed the suction to be the inherent suction from the machine. This differs from the traditional technique with the Hansatome microkeratome (Bausch & Lomb) in which the surgeon presses down during surgery.

These two characteristics, the 19-mm suction ring and no z-axis forces gave us excellent suction, and we were able to safely perform the neutral-to-z-axis technique. Most importantly, we achieved predictable thin flaps (mean: 105 µm; SD: 9.8).

We modified the technique slightly for the second eye since use of the same microkeratome blade as was used for cutting the flap on the first eye customarily produces a thinner flap than was made on the first eye. Thus, for second eye, we continued to use the neutral-to-z-axis technique, but used the 20-mm suction ring instead of the 19-mm. We found that the 20-mm ring gave us flaps close to 100-µm on the second eye as well (mean: 94.5 µm; SD: 7.0). We also found the approximately 100-µm flaps were no more difficult to handle than thicker flaps and no more prone to striae or wrinkles. Essentially, they were identical for ease of handling and incidence of complications.

Table: Results of Patients Who Underwent SBK for Treatment of Myopia

	First eye N=20 19-mm suction ring, 9.5 mm diameter	Second eye N=12 20-mm suction ring, 9.5 mm diameter
Mean Age (SD) Min, Max	38.7 (12.5) 20, 67	
Mean Corneal Thickness µm Preop (SD) Min, Max	544.7 (31.6) 514,653	533.6 (16.1) 514-578
Mean Corneal Thickness µm Postop ± (SD) Min, Max	439.3 (25.4) 413, 519	439.1 (19.9) 418, 493
Difference Pre/Post µm (SD) Min, Max	105.4 (9.8) 93, 134	94.5 (7.0) 84, 107

In performing SBK, we found that the Zyoptix XP microkeratome had resolved many of the weak points of flap creation that potentially existed with older-generation thicker LASIK flaps.[8] Our initial experience suggests the Zyoptix XP can be used with a new technique to give reproducibly thin sub-Bowman's flaps. Flaps created with the XP are planar and provide an even stromal bed. Buttonholes or free caps are rare with the XP. The XP flap can be tailored for each individual eye in diameter, hinge position and centration on the cornea. The Zyoptix XP shows significantly less variation in flap thickness than the Hansatome and is less affected by measurable preoperative variables such as spherical equivalent. In a recent study, both the 60 kHz IntraLase femtosecond laser and the Zyoptix XP 120-µm head and a new blade produced smooth, good quality, compact stromal beds qualitatively and quantitatively.[9]

Our study has the weakness inherent in small patient numbers, and our results need to be confirmed by a study with a larger number of patients. Also, we used subtraction pachymetry to determine flap thicknesses, which has been a standard pachymetric technology used to measure flaps. However, as both the Zyoptix XP microkeratome and femtosecond keratomes have improved the predictability of flap thickness, the variability of the actual flap thickness obtained may have become lower than the variability of the technique for measuring the thickness. OCT is now the more advanced technology for measuring the thickness and may have provided more accurate results for our patient data than subtraction pachymetry.

Given the apparent advantages of SBK with the XP microkeratome, one might ask if the days of traditional LASIK are numbered. While enthusiasm for SBK is clearly justified, patients will continue to ask for LASIK because of its record and word-of-mouth reputation. Surgeons who strive to deliver the safest procedures and optimal quality of vision along with the advantages of any new procedures might consider making the change to SBK, as this new technique will facilitate a relatively easy transition. The SBK procedure may have to reach critical mass to develop the positive word-of-mouth reputation LASIK developed with time. In the meantime, the surgeon can enjoy performing SBK effectively and safely without the need to procure an entirely different set of flap making equipment. **OM**

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