

ASCRS 2001 SAN DIEGO SUBMISSIONS

- LASIK VISION CORPORATION

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COURSES:***Mysteries of Refractive Surgery Revealed by 3D Very High-Frequency Digital Ultrasound Scanning***

Dan Z Reinstein, MD MA FRCSC

High-resolution imaging and pachymetry (1-micron) by VHF digital ultrasound has enabled 3D pachymetry of the corneal epithelium, flap and residual stromal bed, plus sulcus-to-sulcus and angle-to-angle biometry. LASIK Epithelial remodeling and corneal biomechanics, Intacs, 3D flap thickness, 3D predictability of LASIK residual stroma and ectasia plus ultrasound guided customized ablation and wave-front correction will be discussed.

Objective: To understand how epithelial, biomechanical and safety dynamics interact in LASIK, Intacs, customized ablations and phakic IOL technology.

The Science of LASIK

Dan Z Reinstein, MD MA FRCSC, Timothy N. Turner, PhD

Modern diagnostic techniques including the Orbscan, Aberrometry and 3D VHF digital ultrasound scanning have enabled ocular wavefront measurement, biometry of corneal surface curvatures and epithelial, flap and residual stromal thickness mapping with unprecedented accuracy. The inaccuracies of LASIK will be explored in terms of the corneal biomechanics of keratectomy and epithelial and stromal changes in wound healing.

Objective: To understand the current hurdles and issues for accurate customized ablation of the cornea.

PAPERS:***Multi-center LASIK outcomes in myopia using the Technolas 217C in over 20,000 eyes***

Dan Z Reinstein, MD FRCSC; Jonathan D Carr, MD FRCOphth; William B Threlfall, MSc; Randall Cook, BPharm; Emma Cremonesi, MD; Hugo FS Sutton, MD FRCSC

Purpose: To examine the outcomes of primary LASIK for myopia in a high-volume multi-center group surgical practice.

Method: A computerized, intranet, active surveillance outcome analysis system was implemented allowing patient outcome data collection within a system of 15 clinics in Canada from 32 surgeons. Patient data was acquired prospectively in randomized fashion for a 6 month period. Efficacy, accuracy, safety and accountability were determined for eyes with at least 1 month follow-up.

Results: Of 28,606 eyes tracked, 21,069 (73.65%) possessed accountable data. Spherical equivalent myopia ranged from -0.50 to -12.88. Mean follow-up was 2.12 months. For cylinder up to -1.00 DC, analysis was separated in to ranges: Group I: from -0.5 to -2.99; Group II: -3.00 to -4.99D; Group III: -5.00 to -6.99D; Group IV: -7.00 to -9.00D, Group V: above -9.00. Efficacy (UCVA 20/25 or better) was 95.5%, 88.7%, 79.4%, 72.7%, 62.4% respectively. Accuracy (post-op spherical equivalent within 0.5D) was 92.3%, 83.7%, 72.3%, 64.0%, 54.0% respectively. Safety (loss of 2 lines BSCVA) was 0.14%, 0.31%, 0.47%, 1.56%, 0.92% respectively, or 0.37% for all eyes combined.

Conclusion: This is the largest cohort reported to date with high and statistically significant accountability, demonstrating very high quality surgical outcomes and safety for primary LASIK.

Multi-center refractive outcome of lasik for correction of myopia in 1561 eyes using a VISX S2 laser

Jonathan D Carr, Dan Z Reinstein, W Threlfall

Purpose: To report the efficacy of LASIK for correction of myopia using the Visx S2 excimer laser at 12 refractive surgery centers.

Methods: A retrospective analysis was conducted to identify eyes with spherical myopia that underwent LASIK at 12 clinics in the US. A standardized surgical technique was employed. Statistical analysis was performed to determine if the results of spherical ablation were different among the 12 clinics.

Results: Data were available for 1561 eyes. Mean preoperative spherical equivalent was $-3.6D$ ($\pm 0.36D$ S.D.; range -0.63 to -11.5). Mean follow up was 2 months (Range 2 weeks to 4 months). 91.6% of eyes were within $\pm 0.50D$ of emmetropia. 82.8% of eyes achieved uncorrected visual acuity of 20/20 or better. Three eyes (0.2%) underwent enhancement during the follow up period. There was no statistically significant difference in predictability or uncorrected visual acuity among the 12 surgery centers ($p=0.44$)

Conclusion: The Visx S2 excimer laser is effective at correcting myopia. The reproducibility of the outcome across the 12 surgery centers supports the widespread use of the Visx S2 laser and the use of a standardized surgical technique.

Multi-center stratified outcome of LASIK for correction of myopic astigmatism in 3703 eyes using a VISX S2 laser

Dan Z Reinstein, MD FRCSC; Jonathan D Carr, MD FRCOphth; William B Threlfall, MSc; Randall Cook, BPharm; Emma Cremonesi, MD; Hugo FS Sutton, MD FRCSC

Purpose: To report the efficacy of astigmatism correction using the Visx S2 excimer laser.

Methods: A retrospective analysis was conducted to identify myopic astigmatic eyes that were treated at 12 clinics. Eyes were stratified into five groups: 0.5 to 1D, 1-2D, 2-3D, 3-4D, and above 4D. Vector analysis was performed to determine: the percentage reduction of cylinder in the preoperative axis (on-axis), the magnitude of off-axis induced astigmatism, and the axis error. Statistical analysis was performed to determine if the results of toric ablation were different among the 12 clinics.

Results: Data were available for 3703 eyes. Mean preoperative sphere was -3.65D ($\pm 2.13\text{D}$ S.D.); mean preoperative cylinder was -1.14 ($\pm 0.74\text{D}$ S.D.). Mean follow up was 2 months (± 0.75 S.D.). On axis cylinder was reduced by 95% ($\pm 34\%$); 0.01D of cylinder was induced off axis (± 0.25); mean axis error was -0.3° (± 9.5 S.D.).

Mean reduction of on-axis cylinder was 94%, 93%, 97%, 93% and 89% for up to 1D, 1-2D, 2-3D, 3-4D, and above 4D respectively ($p > 0.05$). There was a small but significant difference in the percentage reduction of on-axis cylinder among the 12 clinics ($p = 0.00001$)

Conclusion: The Visx S2 excimer laser is effective at correcting myopic astigmatism. Meticulous attention to preoperative cylinder magnitude and axis measurement together with standardized laser alignment technique should equalize the results among surgeons.

Use of Orbscan to diagnose biomechanical and epithelial changes in LASIK

Cremonesi E, Reinstein DZ, Sutton HFS

Purpose: To use Orbscan back surface data in conjunction with observed refractive data to infer biomechanical and epithelial changes and explain imperfect LASIK outcomes.

Method: Orbscan front and back surface curvatures were determined before and after cases with residual refractive errors. Change in radius of curvature of the back surface was assumed to represent biomechanical corneal change. Front surface radius biomechanical change was assumed to be equal to back surface radius change. This allowed the corneal power shift due to biomechanics to be calculated (assuming thin lens behavior/formulae). The difference between the calculated biomechanical refractive shift and the observed manifest refractive shift was assumed to be due to epithelial changes. Eyes were analyzed using the model, including (a) A -10.63 D myope with post-operative refraction at 1 week of +4.50 D and at 2 weeks +1.25 and (b) A patient who after myopic LASIK for -6.88 D underwent enhancement for residual -1.38 D resulting in little change to -1.25 D post-enhancement.

Results: Patient (a) demonstrated at 1 week a biomechanical steepening of -1.69 D due to “bowing” and an epithelial flattening (lack of steepening) of +6.19 D; from 1 to 2 weeks there was a biomechanical flattening of +0.88 D with an epithelial regression of -4.13 D. Patient (b) demonstrated that after the first treatment 94% of the refractive error of -1.38D was due to biomechanical steepening while only 6% was due to epithelial regression (steepening). Following enhancement, there was a further biomechanical steepening of -1.01 D and an epithelial shift of -0.24 D explaining the apparent lack of response to enhancement surgery.

Conclusion: Orbscan data can be useful in the diagnosis of ametropia after LASIK and may help prevent inappropriate enhancement surgery.

Prospective randomized single blind trial of standard PRK vs. epithelial autograft PRK

Cremonesi E, Reinstein DZ, Threlfall WB, Sutton HFS

Purpose: To determine if epithelial autografting over photorefractive keratectomy improves subjective patient comfort measures and visual recovery time versus standard PRK.

Method: Consecutive patients requesting PRK in a high-volume refractive surgery practice were recruited for study. Patients eyes were randomized intraoperatively to receive an autograft of their own epithelium, loosened by ethanol 20% and atraumatically retracted on a superior hinge. The fellow eye served as control by receiving the exact same epithelial removal technique without it being returned to the stromal bed at the end of the ablation. Patients were "blind" as to the method used for either eye. Evaluations on days 1, 3, 5 were performed including: UCVA, BSCVA, refraction and a subjective analog grading score for symptoms of comparative vision, pain, itchiness, gritty-sensation, dryness and glare. These scores were assessed as continuous variables by multivariate regression.

Results: Six patients were available for analysis at the time of writing. There were no significant differences in any of the scores between autografted and standard PRK.

Conclusion: This small series demonstrated no improvement in symptoms or visual recovery time by the use of an epithelial autograft in PRK. Recruitment of patients continues, and the results from 19 further patients will be presented.

High Volume LASIK Surgery - Safe and Effective?

Dr. Steven Wong - Sacramento

Purpose: To determine the safety and efficacy of Lasik for myopia in the range of -0.5 diopter to -9.00 diopter in a high-volume practice.

Method: A retrospective study was conducted on 601 eyes which had myopic LASIK surgery performed over a three month period. All surgery was performed by one surgeon. All patients were operated on using the same laser (VISX STAR S2), nomogram settings, keratome (Hansatome), surgical technique, and post-operative medications. All patients were refracted by the surgeon pre-operatively. Eyes with at least 1 month of follow-up were included for analysis. The efficacy, accuracy, and safety were determined for this group of eyes.

Results: 200 of 601 eyes were found to meet the study selection criteria. These eyes were grouped according to their pre-operative spherical equivalent refraction. Eyes were assigned into the following spherical equivalent groupings: Group 1: from -0.50 to -2.99D; Group 2: from -3.00 to -4.99D; Group 3: from -5.00 to -6.99D; Group 4: from -7.00 to -9.00D. Efficacy (UCVA) of 20/25 or better was 100%, 86%, 92%, 69% respectively. Accuracy (within 0.5D of intended) was 100%, 86.49%, 87%, and 54%, respectively. No eyes lost 2 or more lines of BSCVA.

Conclusions: Myopic LASIK is very safe and highly efficacious for the correction of myopia in the range of -0.5 to -9.00D in a high volume setting.

VISX S2 Lasik Results for Myopia in a High Volume Setting

Michael Mockovak - San Francisco

Purpose: To determine the success and safety of LASIK for myopia for a single surgeon in a high volume practice.

Method: A random sample of 893 eyes in patients who underwent LASIK over a two month period were included for study. All patients underwent LASIK by the same surgeon, VISX S2, Hansatome, employing the same nomogram, and surgical technique. All patients were refracted pre-operatively by the surgeon. Efficacy, accuracy, and safety were determined for patients with at least 1 month follow-up data.

Results: Data was available for 408 eyes (45%). Analysis was stratified into six groups according to spherical equivalent: Group I: -0.50 to -2.99 D; Group II: -3 to -4.99 D; Group III: -5 to -6.99 D; Group IV: -7 to -8.99 D; Group VI: the entire cohort. Patients in each group had varying amounts of minus cylinder. Efficacy was as follows: UCVA f 20/20 or better: 76%, 69%, 66%, 37%, respectively. 20/25 or better: 88%, 80%, 86%, 60%, 74%, and 81% respectively. 20/40 or better: 97%, 97%, 97%, 88%, 100%, and 96% respectively. Accuracy: 88% of all eyes were within 0.5 D of intended post-operative refraction and 97% within 1.0 D of intended post-operative refraction. Three eyes lost more than one line of best spectacle corrected visual acuity.

Conclusions: The VISX S2 and the Hansatome with the surgical technique used produced effective, accurate, and safe lasik results for the correction of myopia in a high-volume setting.

LASIK outcomes in myopia in a high-volume setting

Mounir Bashour, MD - Toronto/Miss

Purpose: To determine the refractive outcome of LASIK for myopia ranging from -0.5 to -8.99 spherical equivalent in a high-volume LASIK setting.

Method: 1056 of 1560 eyes (67.7%) were found to have at least 1 month follow-up after myopic LASIK and were included for analysis. All patients were operated on using the same laser (Chiron Technolas 217-C), nomogram settings, keratome (Hansatome) and intra-operative technique. The surgeon refracted all patients pre-operatively. Efficacy, accuracy and safety were determined.

Results: Efficacy, accuracy and safety were determined for the following groupings: Group I: from -0.5 to -2.99; Group II: -3.00 to -4.99D; Group III: -5.00 to -6.99D; Group IV: -7.00 to -8.99D. Efficacy (post-operative UCVA of) 20/25 or better was 95.3%, 93.9%, 82.3% and 79.7%, for groups I, II, III and IV respectively. Accuracy (post-operative refraction within 0.5D of intended) was 94.1%, 88.5%, 68.3% and 64.4%, for groups I, II, III, and IV respectively. Safety: loss of more than 2 lines of BSCVA was found in 0.35% for the series.

Conclusions: The Chiron Technolas 217 coupled with the surgical technique employed produced highly efficacious, accurate and safe outcomes for the correction of low/moderate myopia in a high-volume setting.

Efficacy, Accuracy, and Safety of Lasik in a High Volume Surgical Setting***Using the VISX Star S2***

Joseph King, MD - San Diego

ABSTRACT:

PURPOSE: To determine the refractive outcome of LASIK for myopia ranging from -0.75 to -8.99 in a high-volume LASIK setting.

METHOD: 773 of 776 eyes were found to have at least 1 month follow-up after myopic LASIK in a random sample of eyes, and were included for analysis. All patients were operated on

using the same laser (VISX S2), nomogram settings, keratome (Hansatome) and intra-operative technique. All patients were refracted by the surgeon pre-operatively. Efficacy, accuracy and safety were determined.

RESULTS: Efficacy, accuracy and safety were determined for the following groupings: Group I: from -0.5 to -2.99; Group II: -3.00 to -4.99D; Group III: -5.00 to -6.99D; Group IV: -7.00 to -8.99

Efficacy (post-operative UCVA of 20/25 or better) was 94%, 89%, 84% and 90%, for groups I, II III, and IV, respectively. Accuracy (post-operative refraction within 0.5D of intended) was 93%, 89%, 79% and 83%,for for groups I, II, III, and IV respectively.

Safety (loss of more than 2 lines of BSCVA) was found to be 0.0% for for all groups.

CONCLUSIONS: The VISX S2 coupled with the surgical technique employed produced highly efficacious, accurate and safe outcomes for the correction of low/moderate myopia in a high volume setting.

Safety in Numbers? Early Results of High Volume Laser In Situ Keratomileusis with the VISX STAR S2.

Ketan H. Patel, MD

Purpose: To assess the refractive outcome, safety, and accuracy of laser in situ keratomileusis (LASIK) for mild to moderate myopia in a high volume LASIK setting.

Methods: Five month prospective operative data were collected from 621 of 769 eyes with fogged manifest spherical myopia of -0.50 to -6.99 diopters (D) and at least one month follow up. The surgeon (KHP) refracted all patients pre-operatively. All were operated on by KHP with the VISX STAR S2 Excimer Laser System (Visx, Inc., Santa Clara, CA), Hansatome microkeratome (Bausch & Lomb Surgical, Inc., Claremont, CA), same nomogram settings, and same operative technique. Efficacy (post-operative uncorrected visual acuity (UCVA) of 20/25 or better), accuracy (post-operative refraction within 0.50 D of intended), and safety (the loss of more than two lines of best spectacle corrected visual acuity (BSCVA)). Efficacy, accuracy and safety were determined for the following pre-operative refraction groupings: Group I (-0.5 to -2.99 D), Group II (-3.00 to -4.99 D), and Group III (-5.00 to -6.99 D).

Results: Efficacy was 97%, 90%, and 92% for groups I, II, and III respectively. Accuracy was 95%, 85%, and 79% for groups I, II, and III respectively. Safety was found to be 0.0%, 0.9% and 0.9% for groups I, II, and III respectively.

Conclusions: These data suggest that LASIK for mild to moderate myopia (-0.5 to -6.99 D) using the VISX STAR S2 with the surgical technique and nomogram employed in a high volume environment is highly efficacious, accurate and safe.

LASIK in HIV+ Patients

Michael E. Mockovak, MD, Sasha Penn, OD, Denis Finney, OD, Justin Graham, MD, Howard Rice, MD, James Abrams, MD, Michael Gorin, MD, Bryan Doherty, OD

Purpose: To report the outcomes of 39 eyes in 20 HIV+ patients who underwent LASIK.

Methods: The medical records of 20 HIV+ patients who underwent LASIK were reviewed. Pre-operative ocular data, operative complications, and post-operative results were analyzed. The system parameters recorded were: CD4 counts, viral loads, antiretroviral medications, history of opportunistic infections, and co-morbid conditions.

Results: Thirty-nine eyes of twenty patients who were HIV+ underwent LASIK. All patients had pre-operative myopia. Pre-operative sphere ranged from 0 to $-8.50D$ with an average of $-3.27D$. Pre-operative cylinder ranged from 0 to $-2.25D$ with an average of $-0.97D$. The VISX S2 was used in 37 cases. The Technolas 217 was used in 2 cases. The Bausch & Lomb Hansatome was used in all cases. The surgery in 36 eyes was uncomplicated. The surgery in 3 eyes was complicated by epithelial defects associated with microkeratome passage over the cornea. A contact lens was placed on each of the three eyes immediately post-operatively. There were no adverse sequelae in any of these three eyes. The post-operative visual acuity results were: 57% 20/20 or better, 78% 20/25 or better, and 100% 20/30 or better. No eyes lost two or more lines of best-corrected visual acuity. There were no post-operative complications. There was no correlation between system parameters and ocular results.

Conclusion: HIV disease is a potentially fatal illness. Excimer laser surgery on HIV patients is not approved by the FDA. With the advent and success of new antiretroviral therapies, the prognosis for HIV patients is greatly improved. While much more study is needed, these initial results suggest that HIV+ patients may be reasonable candidates for LASIK.

LASIK Treated Mixed Astigmatism Using Cross Cylinder Ablation on the Bausch & Lomb 217C Laser

Avi A. Wallerstein, MD, FRCSC, Mark J. Cohen, MD, FRCSC, Dan Z. Reinstein, MD, FRCSC, Myriam Assouline, BScN, MHA, Pierre Demers, MD, FRCSC

Purpose: To evaluate the efficacy, accuracy and safety of the treatment of mixed astigmatism using the B & L 217C laser with a crossed cylinder ablation protocol. **Methods:** The B & L 217C laser with the Hansatome was used in all 156 LASIK cases. The steep axis (myopic astigmatism) was flattened and the flat axis (hyperopic astigmatism) was steepened, avoiding redundant ablation. The axis with the greatest magnitude of power was treated first. Vector analysis was performed using standard angle-doubling methodology. **Results:** Mean pre-op spherical equivalent was 0.27D (SD 0.65). Mean total pre-op cylinder was 3.1D (SD 1.0, range 1.3 to 6.0D). The mean available follow-up data was 4.2 months, with 90 eyes having data for 6 months or longer. **Vector analysis:** Mean post-op on-axis residual astigmatism was 0.03D (SD 0.76). The mean off-axis-induced cylinder was 0.03 D (SD 0.59). **Safety:** Pre-operative or better BSCVA was achieved in 87.2% of 154 eyes. 8.7% lost 1 line of BSCVA, and 2.8% lost 2 lines. One eye lost 3 lines (0.8%), but no eyes lost below the 20/30 level. 17.4% gained from 1 to 4 lines of BSCVA. **Efficacy:** 90%, 97%, and 100% achieved 20/20, 20/25 and 20/30 vision respectively. No eyes achieved less than 20/30 UCVA. The mean central ablation depth was only 35.6 microns. **Conclusion:** The B & L 217C laser, with crossed-cylinder ablation protocol is both safe and highly effective, removing minimal corneal tissue and producing excellent post-operative visual results in the treatment of mixed astigmatism up to 6.00 D.

Bausch & Lomb Technolas 217C and Hansatome for the correction of myopia with a standardized LASIK technique

Bruce Pretty, MD FRCSC, James McNeil, MD FRCSC; David Andrews, MD FRCSC; Dan Z Reinstein, MD MA FRCSC;

Purpose: To determine the efficacy, accuracy and safety of myopic LASIK in a group practice with standardized surgical technique and instrumentation

Method: Randomized patients with cylinder less than or equal to -1.00 DC were included for study prospectively. All patients underwent refraction by their respective surgeon. Patients were divided into groups according to spherical equivalent for the analysis.

Results: Of 2549 eyes recruited for study, 2250 (88.3%) had at least 1 month follow-up data, with mean follow-up time of 2.7 months. "Perfect" efficacy, defined as UCVA 20/20 or better was as follows: For myopia up to -3.00 D = 70%; -3.00 to -5.00D = 84%; -5.00 to -7.00D = 57%; -7.00 to -9.00D = 60%. "Near perfect" efficacy, defined as UCVA 20/25 or better was as follows: For myopia up to -3.00 D = 93%; -3.00 to -5.00D = 85%; -5.00 to -7.00D = 77%; -7.00 to -9.00D = 76%. Accuracy (within 0.5D of intended): for myopia up to -3.00D = 91%; -3.00 to -5.00D = 80%; -5.00 to -7.00D = 71%; -7.00 to -9.00D = 72%. Six eyes lost 2 or more lines of BSCVA (0.27%).

Conclusion: The tracker assisted Technolas 217C, Hansatome and standard surgical technique employed resulted in very high efficacy and safety for the correction of myopia.

LASIK correction of hyperopia and astigmatism using the Bausch & Lomb Technolas 217C and Hansatome

James McNeil, MD FRCSC; Bruce Pretty, MD FRCSC; David Andrews, MD FRCSC; Dan Z Reinstein, MD MA FRCSC

Purpose: To determine the efficacy, accuracy and safety of hyperopic LASIK with astigmatism

Method: Consecutive patients were included prospectively. Patients were divided into groups according to spherical equivalent for efficacy and accuracy analysis. Refraction was entered directly into the laser (plus cylinder format) without surgeon nomogram adjustment. Vector analysis was performed to determine efficacy of toric correction.

Results: Of 153 eyes recruited for study, 138 (90.2%) had at least 1 month follow-up data. Efficacy, defined as UCVA 20/25 or better was as follows: For hyperopia +1.00 to +3.00 D = 74.5%; +3.01 to +4.00D = 56%. Accuracy (within 0.5D of intended): for +1.00 to -3.00D = 69%; +3.01 to +4.00D = 52%. Linear regression of attempted vs. achieved showed a tendency for undercorrection (slope 0.8). Safety: 1.68% lost 2 lines, no eyes lost more than two lines BSCVA. Vector analysis: 41 eyes had cylinder -1.00 to -4.75 DC. Mean pre-op was -1.74 DC, mean on-axis treated was -1.81 DC (110%). Mean surgically induced astigmatism was 1.89 DC with an axis mean error of +2.4 degrees (clockwise) and SD = 9.4 degrees (range 60 degrees).

Conclusion: The tracker assisted Technolas 217C, Hansatome and standard surgical technique employed resulted in good visual efficacy below +3.00, but reduced above this level. Nomogram adjustment would significantly improve the efficacy. There was a small on-axis cylinder over-correction, with a noticeable spread in the angle of error of the surgically induced astigmatism.

Thin Button Hole Flaps in Hansatome Lasik Surgery

Avi A. Wallerstein, MD, FRCSC, Mark J. Cohen, MD, FRCSC, Jonathan Carr, MD, FRCSC, Myriam Assouline, BScN, MHA, Dan Z. Reinstein, MD, FRCSC

Purpose: To report the incidence, risk factors, and outcomes for thin button hole flaps (TBH) in Lasik surgery. Methods: 21,000 Lasik Hansatome surgeries were retrospectively reviewed to reveal 32 TBH flaps. Descriptive statistics and chi squared testing was used for analysis. Results: The incidence of TBH flaps was 1.5 per 1000 eyes. Age, gender, contact lens wear, IOP, corneal diameter and thickness, keratometry, Hansatome head (180 um vs 160 um), suction ring size, and surgeon experience had no significant correlation. There was a tendency towards higher keratometry (60% above 46D). 24/32 TBH flaps (75%) occurred in the second of two treated eyes ($p < 0.01$), independent of the above variables. There was no significant change in spherical equivalent pre to post TBH flaps ($R^2 = 0.9771$). There was a tendency toward reduction in cylinder magnitude post TBH flap ($R^2 = 0.1507$). Safety: 23 eyes (72%) had no change in BSCVA with 5 eyes (16%) losing one line and one eye (3%) losing two lines BSCVA. 10 eyes (31%) had mild flap striae requiring no treatment, with no cases of central epithelial ingrowth after a mean follow of 5.5 months. Conclusion: Flaps created in the second treated eye are significantly more likely to develop a TBH flap. The long-term safety profile of this complication is good.

