

Patient Preference Testing on the Surgical Experience and Early Postoperative Period After Undergoing Bilateral Lenticule Extraction With ZEISS SMILE pro

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Introduction

The safety and efficacy of lenticule extraction with SMILE® and SMILE® pro from ZEISS have been well documented since it was first approved outside the United States in 2011 and FDA approved in 2016.¹⁻⁵ To enhance the understanding of the patient experience, patient reported outcomes have become more widely utilized to capture subjective satisfaction scores and feedback regarding the surgical experience. In recent years, patient reported outcomes have played a larger role in comprehensively evaluating the success of healthcare treatments. Landmark studies such as the PROWL-1 and PROWL-2 studies shed light on the importance of utilizing patient reported outcomes to aid in the assessment of symptoms and satisfaction after Laser-Assisted in Situ Keratomileusis (LASIK) surgery.^{6,7} The studies focused on a standardized approach to assessing the subjective patient experience to help aid in better patient counseling and expectation management. Various validated questionnaires have also been developed, such as the QIRC, QoV, Refractive Status Vision Profile survey, National Eye Institute Refractive Error Quality of Life Measurement, NEI VFQ, and others.⁸

The number of studies addressing patient reported outcomes for lenticule extraction is limited. The studies that have collected patient feedback typically focus on results at 1, 3, or 6 months after treatment.⁹⁻¹² Collecting this data at later time-points, while important, misses a critical component of patient satisfaction in evaluating the surgical and early postoperative experience.

The introduction of the latest femtosecond (fs) laser from ZEISS, the VISUMAX® 800, has established a new standard in the speed of laser application for lenticule creation. Combined with the curved patient interface, open-air design, and the ability to pair with different patient support systems, the ZEISS VISUMAX 800 addresses the often-overlooked aspects of patient comfort.

The aim of this marketing study was to collect patient feedback of the surgical experience and visual satisfaction during the early postoperative period after undergoing ZEISS SMILE pro with the ZEISS VISUMAX 800.

Materials and Methods

This marketing study was performed at four sites in the United States between June 2024 and November 2024. All study locations were experienced in Lenticule Extraction with each surgeon followed their clinic's standard operating procedure, which included the use of topical numbing agents and preoperative oral anxiolytics. Patients undergoing ZEISS SMILE pro in routine use of the laser were asked if they would participate in filling out a questionnaire after treatment. Willing participants were instructed to complete the questionnaire within 24 to 36 hours after treatment. The questionnaire was divided into two sections. The first three questions were used to gauge eligibility and qualify patients:

1. Has it been 24-36 hours since completing SMILE surgery?
2. Where did you have your surgery?
3. Please provide your initials and date of birth.

The remaining eleven questions utilized Likert-scaled or multiple-choice selection to gather data about the patient experience. The results were analyzed using descriptive statistics. The frequency and percentage of each response category were calculated for Likert-scale questions, along with the mean satisfaction scores and standard deviation. For multiple-choice questions, the percentage of respondents selecting each option was summarized.

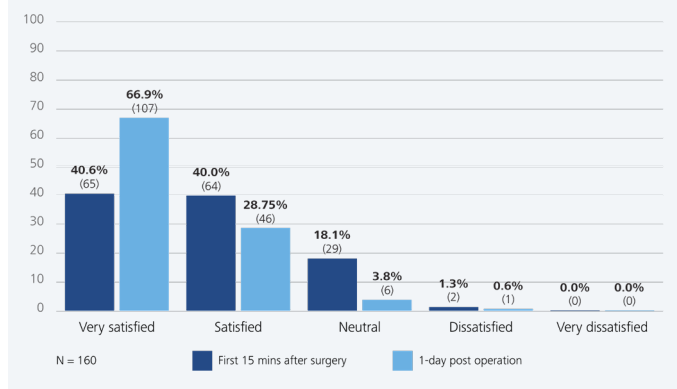
Results

A total of 160 patients elected to participate in completing the questionnaire during the enrollment period. The average age of the participants was 35 years of age [SD± 7.82] (Appendix A. Supplementary Data).

Early Postoperative Vision

The questionnaire evaluated satisfaction with the postoperative vision immediately after surgery (within 15 minutes of the procedure) and again at the 1-day postoperative visit. The majority of patients (80.6%) reported being 'very satisfied' or 'satisfied' with their vision immediately after the procedure. The number increased at the 1-day postoperative visit with 95.7% of patients reporting being 'very satisfied' or 'satisfied' with their vision.

Figure 1: Postoperative vision satisfaction scores measured 15 minutes after ZEISS SMILE pro (same day) and 1-day (24-36 hours).

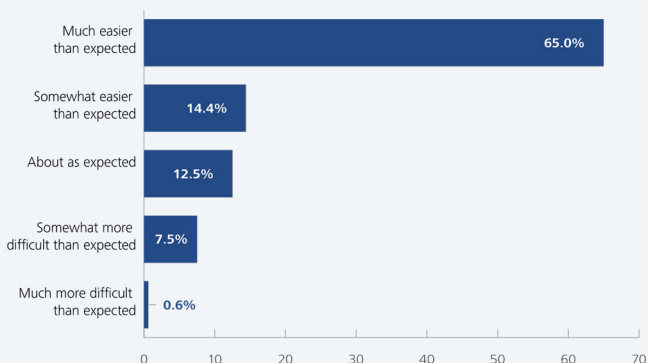


Perceived Pain and Anxiety Levels

The findings indicate that the majority of patients (96.3%) reported minimal to no pain while undergoing ZEISS SMILE pro. During treatment, most patients felt either no or mild pressure on the eye. When evaluating the effect any pressure had on the vision, 'nothing happened with my vision' and 'I don't recall' accounted for 25% of the responses. Of the remaining responses, the most common finding was 'vision went white' (30.6%). The questionnaire showed that 78.1% of patients reported 'no anxiety' or 'some anxiety' while undergoing the procedure, with a majority of patients (91.9%) expressing the procedure as being 'much easier than expected', 'somewhat easier than expected' or 'about as expected' compared to their presurgical expectations. Lastly, the findings indicate that 96.9% of patients felt the procedure duration either 'greatly

enhanced comfort', 'somewhat enhanced comfort', or had 'no effect on comfort', suggesting that a majority had their comfort expectations met or exceeded. Additionally, 94.4% of patients felt ready to return back to their normal activities within 24 to 36 hours after having ZEISS SMILE pro.

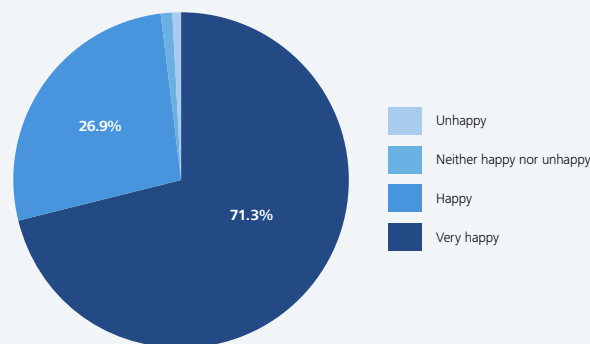
Figure 2: Comparison of presurgical expectations versus actual post-surgical experience (e.g., ease of procedure) after ZEISS SMILE pro.



Overall Surgical Experience

The survey indicated that 98.1% of patients reported feeling either very happy or happy after undergoing the procedure, indicating a strong sense of overall satisfaction and positive experience. When asked if patients would recommend ZEISS SMILE pro to a family member or friend, 98.1% of participants responded that they would highly recommend or recommend the procedure.

Figure 3: 1-day postoperative happiness following ZEISS SMILE pro, assessing overall patient satisfaction with vision recovery.



Discussion

Lenticule extraction with ZEISS SMILE and SMILE pro have collectively surpassed over ten million procedures worldwide. The adoption rate of this technology is even more impressive when considering that over the past eight years, ZEISS SMILE procedure volume has grown by 900%.¹³ The increased laser pulse rate of 2 MHz of the ZEISS VISUMAX 800 offers surgeons a faster cutting speed compared to ZEISS VisuMax, a feature that may promote further adoption of lenticule extraction. Additional intelligent assistance systems such as OcuLign® for cyclotorsion alignment and CentralLign® for centration assistance provide enhanced precision and control during laser application. The added features of the ZEISS VISUMAX 800, combined with ZEISS SMILE pro software, enable surgeons to broaden their clinical offerings to prospective refractive surgery candidates with confidence of providing an excellent intraoperative and immediate postoperative patient experience.

The SMILE pro Patient Preference Questionnaire demonstrated high patient satisfaction with the intraoperative experience. Ninety-six percent of patients reported mild to no pain when undergoing ZEISS SMILE pro, with a majority of patients stating they felt minimal to no pressure. Visual symptoms during the laser treatment were also recorded, with the most common reports including the vision went white (30.6%), vision faded (9.4%), other (3.8%), and the vision going black (2.5%). Reports of the vision going white can be attributed to the bubble pattern created during lenticule creation which is subsequently removed during surgical dissection. Vetter et al.'s¹⁴ comparison of intraocular pressure (IOP) across different femtosecond laser platforms also supports the low rate of vision blacking out when utilizing ZEISS VISUMAX technology. Beyond showing the most favorable IOP values across the laser platforms evaluated, the concave laser contact glass helps to displace less volume during treatment, allowing patients to continue fixation throughout laser application.

A majority of patients within the survey reported minimal to no anxiety while undergoing ZEISS SMILE pro, with 91.9% of participants stating their surgical experience was easier or met their presurgical expectations. Additionally, the survey revealed that ZEISS SMILE pro provides a surgical experience that either meets or exceeds comfort level expectations.

Interestingly, previous studies have found that patients tend to be more fearful of suction application with LASIK than ZEISS SMILE,^{9,10} with Damgaard et al.⁹ reporting that excimer ablation in LASIK was the most frightening step of the two procedures in their randomized paired-eye study. It has been postulated that the mental imagery of flap creation may account for the fear affiliated with LASIK, which was not seen amongst SMILE participants.¹⁰ Overall, the SMILE pro Patient Preference Questionnaire results align well with the assumption that a decreased laser treatment time with the ZEISS VISUMAX 800 helps to contribute to a positive surgical experience.

Lenticule extraction with ZEISS SMILE pro was also found to afford patients the ability to quickly return to daily activities, including driving, exercising, texting, and reading. Within 24 to 36 hours of having surgery, 94.4% of patients felt ready to return to their daily activities. Reengaging in everyday tasks after lenticule extraction is contingent upon the size of the superior incision and the principles of corneal wound healing. ZEISS SMILE pro allows surgeons to create a superior incision as small as 4 mm which is used to separate and remove the lenticule. This incision is considerably smaller than the circumferential cut needed to create a corneal flap. Flap stability in the early postoperative period is of particular importance as minor insults such as eye rubbing or lid squeezing can cause dislocation. A retrospective case review of 81,238 consecutive LASIK procedures by Clare et al.¹⁵ reported that all flap displacements occurred within 48 hours of surgery. While the incidence of flap dislocation (0.10-0.40%) and visually significant striae (0.6%) is low^{16,17} the study highlights the importance of allowing uninterrupted corneal flap healing and patient education to avoid activities that can lead to eye rubbing or lid squeezing. In contrast, the inherent nature of a lenticule extraction procedure eliminates the concern of flap dislocation. While cap folds and microstriae are still possible, the cause is thought to come from a mismatch in the length of the cap compared to the length of the stromal bed,¹⁸ as opposed to disruption and sliding of the flap adhesion from a LASIK procedure.

Early postoperative healing, specifically the principles of corneal wound healing, also helps to elucidate why ZEISS SMILE pro patients can quickly return to daily activities. Upon completion of the lenticule extraction, wound healing at the incision is triggered by a cascade of complex cellular interactions in distinct phases. Within 24 hours, cellular reorganization and protein syntheses trigger epithelial cell migration, cell proliferation, and differentiation, effectively covering the superior defect.¹⁹⁻²² Additionally, Khamar et al.²³ proposed that wound healing post SMILE surgery may be better compared to LASIK due to decreased expression of pro-inflammatory and neurotrophic markers in human corneas. This is further supported by previous animal studies when evaluating early corneal wound healing after SMILE.^{24,25} While postoperative recovery recommendations may vary amongst providers, the minimally invasive nature of ZEISS SMILE pro allows for limited downtime and a quick return to daily activity.

Early postoperative satisfaction was a key area of the questionnaire that evaluated happiness levels and the willingness to refer friends or family after the procedure. A total of 98.1% of survey participants reported they were happy or very happy after undergoing ZEISS SMILE pro, which aligns with the visual satisfaction values and overall surgical experience. In addition, 98.1% of patients reporting that they would recommend ZEISS SMILE pro to friends or family. This mirrors previous studies evaluating postoperative subjective satisfaction after femtosecond LASIK with linear scoring showing that between 88% and 95% of patients would recommend LASIK to friends and relatives.²⁶⁻²⁸

Lastly, certain limitations can be applied to this study. As acknowledged by previous studies focused on patient reported outcomes for refractive surgery,^{6,8} under or over-reporting is possible due to the Hawthorn effect and sampling bias.

Additionally, while validated questionnaires related to laser vision correction were available, the nature of the study and desired endpoints limited the use of previously established surveys. This led to the development of a study specific questionnaire.

Despite these limitations, the study has strengths in representing a relatively large sample size from a demographically diverse patient population across the United States. This study is also one of the first to qualitatively analyze the surgical patient experience and early visual satisfaction with ZEISS SMILE pro. Further studies can add to the validity of these first-of-kind results and serve as further confirmation of the outcomes reported in this article.

Conclusion

The survey results show an overall positive patient experience both during and in the early postoperative period after lenticule extraction with ZEISS SMILE pro. Most notably, participants reported high visual satisfaction with their 1-day postoperative results, comfort levels that met or enhanced expectations, minimal to no pain or anxiety during the procedure, and ZEISS SMILE pro being perceived as easier than presurgical expectations. When combined with overall happiness levels and willingness to recommend the procedure, ZEISS SMILE pro offered patients a surgical experience that ensured comfort and satisfaction.

Appendix A. Supplementary Data

Table 1. Surgical Experience After Undergoing Lenticule Extraction With ZEISS SMILE pro

Question	Answer	% (n/N)
How much pressure on the eye did you feel during the SMILE procedure?	No pressure	28.8 (46/160)
	Mild pressure	61.3 (98/160)
	Moderate pressure	9.4 (15/160)
	Significant pressure	0.6 (1/160)
	Extreme pressure	0.0 (0/160)
When you experienced pressure, did anything happen to your vision?	Vision went white	30.6 (49/160)
	Nothing happened with my vision	14.4 (23/160)
	I don't recall	10.6 (17/160)
	Vision faded	9.4 (15/160)
	Other	3.8 (6/160)
	Vision went black	2.5 (4/160)
	No responses	28.75 (46/160)
What was your pain level during the SMILE procedure?	No pain	75.0 (120/160)
	Mild pain	21.3 (34/160)
	Moderate pain	3.1 (5/160)
	Severe pain	0.6 (1/160)
	Very severe pain	0.0 (0/160)
What was your anxiety level during the SMILE procedure?	No anxiety	17.5 (28/160)
	Some anxiety	60.6 (97/160)
	Moderate anxiety	13.8 (22/160)
	High anxiety	6.3 (10/160)
	Extreme anxiety	1.9 (3/160)
After completing your SMILE surgery, how would you rate your experience compared to what you expected before surgery?	Much easier than expected	65.0 (104/160)
	Somewhat easier than expected	14.4 (23/160)
	About as expected	12.5 (20/160)
	Somewhat more difficult than expected	7.5 (12/160)
	Much more difficult than expected	0.6 (1/160)
How did the duration of the procedure affect your comfort levels?	Greatly enhanced comfort	52.5 (84/160)
	Somewhat enhanced comfort	28.8 (46/160)
	No effect on comfort	15.6 (25/160)
	Somewhat reduced comfort	1.9 (3/160)
	Greatly reduced comfort	1.3 (2/160)
Have you returned to your full activities of daily life? (driving, exercising, texting, reading, etc.)	Yes, full return to activity	65.6 (105/160)
	No, not returned to activity, but ready to	28.8 (46/160)
	No, not returned to activity, and not comfortable to	5.6 (9/160)
Since undergoing the procedure, how would you rate your overall happiness?	Very happy	71.3 (114/160)
	Happy	26.9 (43/160)
	Neither happy or unhappy	1.3 (2/160)
	Unhappy	0.6 (1/160)
Given your experience, would you recommend the procedure to a friend or family member?	Highly recommend	83.1 (133/160)
	Recommend	15.0 (24/160)
	Undecided	1.9 (3/160)

Table 2. Satisfaction With Vision After Undergoing Lenticule Extraction With ZEISS SMILE pro

Question	Answer	% (n/N)
How satisfied were you with your vision immediately after the procedure (first 15 mins after surgery)?	Very Satisfied	40.6 (65/160)
	Satisfied	40.0 (64/160)
	Neutral	18.1 (29/160)
	Dissatisfied	1.3 (2/160)
	Very Dissatisfied	0.0 (0/160)
How satisfied are you with your vision at 1-day post operation?	Very Satisfied	66.9 (107/160)
	Satisfied	28.75 (46/160)
	Neutral	3.8 (6/160)
	Dissatisfied	0.6 (1/160)
	Very Dissatisfied	0.0 (0/160)

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