Quality of life after refractive surgery: ReLEx SMILE vs Femto-LASIK

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Purpose: The safety and effectiveness of complex myopic astigmatism correction using ReLEx SMILE or Femto-LASIK techniques have been well established. The purpose of the current study is to compare quality of life (QoL) outcomes following ReLEx SMILE or Femto-LASIK procedures in parallel with functional vision and anatomic outcomes of treated eyes.

Patients and methods: This prospective, consecutive series included 118 patients, 18–43 years of age, out of which 56 underwent ReLEx SMILE and 62 underwent Femto-LASIK surgery for correction of myopic astigmatism. All patients underwent standard comprehensive ophthalmic examinations, and additionally, completed The Quality of Life Impact of Refractive Correction Questionnaire to determine the impact the vision-correction treatment had on their QoL.

Results: In both treatment groups, the postoperative refractive outcomes were comparable, with visual acuity improvements for both groups noted the day following surgery. After laser correction of complex myopic astigmatism using Femto-LASIK and ReLEx SMILE methods, the overall QoL indicators are statistically significant (P<0.01) exceeding preoperative values 1 month after the operation and reaching the maximum values by the end of the observation period (P<0.0001).

Conclusion: The results of the study suggest that patients require some time to adapt to their new visual function and its impact on their daily living, delaying detectable improvements in QoL. Moreover, these results may suggest a higher satisfaction trend and long-term QoL in patients undergoing ReLEx SMILE in comparison to Femto-LASIK. Long-term results from the study demonstrated high patient satisfaction with both methods.

Keywords: ReLEx SMILE, Femto-LASIK, quality of life, QoL questionnaire, refractive surgery

Introduction

There are several recognized corneal refractive surgery platforms and techniques to correct myopia, hyperopia, or astigmatism by changing the curvature of the cornea. The evaluation of efficacy and safety of ophthalmic treatments or procedures are conventionally subdivided into objective and subjective assessment categories. Key treatment evaluation indicators include the quantitative outcomes of visual acuity testing (corrected and uncorrected), keratometry, refractometry, contrast sensitivity, corneal high-order aberrations, nerve fiber regeneration, centration of the treatment zone, and corneal biomechanical properties.1-4 Often, patient satisfaction is more subjective and determined by a qualitative comparison of the vision experienced postoperatively, balanced with their preoperative expectations. As the predictability of refractive correction and visual outcomes improve, patient satisfaction and managing patient expectations become key in the context of modern ophthalmology.5 Simply correcting the refractive error is no longer the only consideration, and patients,
particularly those within the working-age population, expect that the procedure will positively influence their quality of life (QoL).

Numerous studies have been published comparing two state-of-the-art vision correction techniques used for correcting complex myopic astigmatism, the ReLex SMILE and the Femto-LASIK.4–11 The safety, predictability, and effectiveness of complex myopic astigmatism correction, using ReLex SMILE or Femto-LASIK techniques, have been well established. The majority of these studies focus on the objective measures for evaluation, yet often neglect the subjective experience or QoL outcomes of the patient.12–21 Few publications compare QoL following ReLex SMILE technique, and a paucity of the literature exists for any comparative measures.13,22,23

QoL combines various aspects, which include physical condition, functional capabilities, psychological state, general condition, and social interaction.24–26 Various QoL questionnaires have been used to evaluate patients’ satisfaction with their life conditions, their work, education, home environment, and even political beliefs in relation to their visual status.

A survey developed and validated by Pesudovs et al, the Quality of Life Impact of Refractive Correction (QIRC) Questionnaire, was specifically developed for patients with refractive error corrected by spectacles, contact lenses, and refractive surgery.27–29 [Our team was granted copyright permission to reproduce the QIRC Questionnaire and the questionnaire items in this paper.]

The purpose of the current study is to compare questionnaire-based QoL of patients following complex myopic astigmatism correction with ReLex SMILE or Femto-LASIK procedures in parallel with functional vision and anatomic outcomes of treated eyes.

**Patients and methods**

This prospective, single-center, consecutive series included 118 patients, age 18–43 years. Fifty-six patients received ReLex SMILE and 62 patients received Femto-LASIK surgery for correction of myopic astigmatism. Procedures were performed from March 2015 to May 2017 by two equally experienced refractive surgeons. The research was conducted at the Krasnodar Branch of Fyodorov Eye Microsurgery Federal State Institution in Krasnodar, Russia. Patients were not included in the series if they had other serious ocular disorders; neurologic and systemic diseases; myopic correction > 8.5 D; corrected vision acuity < 0.1 log MAR (poorer than 20/25 Snellen equivalent); “dry eye” syndrome; epitheliopathy; or previous inflammatory corneal diseases.

This study adhered to the tenets of the Declaration of Helsinki. Each patient included in the study provided informed consent for the procedure and collection of data. This study was approved by the Ethics Committee in the Body of Scientific Medical Board of the Krasnodar Branch of Fyodorov Eye Microsurgery Federal State Institution, Russia.

Patients underwent femtosecond vision correction using ReLex SMILE and Femto-LASIK techniques and laser system VisuMax™ (Carl Zeiss Meditec AG, Jena, Germany) with pulse frequency comprising 500 kHz and laser system EX 500 (Novartis/ALCON/WaveLight, Germany) for complex myopic astigmatism correction. The surgeries were carried out by two equally experienced clinical surgeons using general techniques. The femtosecond laser flaps were obtained using the following settings: thickness 100.72±5.43 µm (from 90 to 110 µm), diameter 8.52±0.32 mm (from 7.9 to 8.8 mm), with a superior hingle in all eyes. The average central optical ablation zone was 6.24±0.42 mm (from 6.0 to 7.0 mm).

Small-incision lenticule extraction (ReLex SMILE) surgeries were performed using the technology described by Sekundo et al.30 The intended thickness of the upper tissue arcade (the cap) was 120 mm, with an intended diameter of 7.5 mm, whereas the average diameter of the refractive lenticule was 6.37±0.44 mm (from 6.0 to 7.0 mm). A single-side cut of 90° with a circumferential length of 3.0–4.5 mm was made in the superior position. Following the cutting procedure, the refractive lenticule was dissected and separated through the side-cut and manually removed.

All patients underwent standard comprehensive ophthalmic examinations, preoperatively and at regular postoperative intervals, including assessment of best-corrected visual acuity (BCVA), manifest and cycloplegic refraction, intraocular pressure assessment by tonometry, corneal topography by Pentacam (Oculus, Germany), determination of endothelial cell count, and dilated examination of ocular fundus with Goldmann lens.

In addition to the traditional clinical assessments, patients completed the 20 items in the QIRC Questionnaire24–29 to determine the impact the vision-correction treatment had on their QoL. Questionnaires were completed preoperatively, and at 1, 3, and 6 months postoperatively. Each question has five possible responses, ranging from “none at all”, “a little bit”, to “a moderate amount”, “a lot”, or “so much that I can’t do this activity”.29
The questionnaire weighs questions and individual responses with a score that can range from 14.39 to 88.21, with higher scores correlating with a more favorable outcome. Questions 1–7 have a range 24.07–65.11 scores, questions 8–13 has a range 28.59–66.62, questions 14–20 has a range 14.39–88.21 scores. Patients were followed for a minimum of 6 months.

### Statistical analysis

Statistical processing and graphical presentation of the results were carried out using the software MS Excel 2016 (Microsoft, USA) and Statistica version 10.0 (StatSoft Inc., Tulsa, OK, USA). The data obtained are presented as the mean and SD (M±SD). For comparison of two independent groups, Student’s unpaired t-criterion was applied, and for comparison of dependent ones, the Student’s t-test was applied. The critical level of significance of the null statistical hypothesis in accordance with the criteria accepted in biomedical research was taken as 0.05.

### Results

The baseline characteristics and demographics of the study cohort are shown in Table 1. Preoperatively and within the postoperative period, no complications or adverse events were observed in any patient. Table 2 includes the uncorrected visual acuity (UCVA) for both groups within different observation periods. In the vast majority of cases, within the first 2 weeks after the refractive procedure, the UCVA was equivalent to the preoperative BCVA.

In both groups, compatible refractive values were reached (Figures 1 and 2). Thus, as a result of applying ReLex SMILE technique, the refractive value of ±0.5 D was achieved in 93.8% of cases and ±1.0 D in 100% of cases. Within the first days postoperatively, an insignificant hypermetropic refractive shift was noted, which stabilized within 1 month, and the achieved planned emmetropia remained sustainable during the full observation period. In the Femto-LASIK group, the planned refractive value of ±0.5 D was achieved in 94.2% of cases and ±1.0 D in 100% of cases.

A comparative analysis the answers of patients in the study groups to the questions of the QIRC questionnaire indicated that prior to surgery, patients in the ReLex SMILE group were more dissatisfied with the quality of sight, dependence on spectacle correction, as demonstrated by their answers to question 11 (P<0.01), questions 5–6 (P<0.01) and question 7 (P<0.05). Analyzing the answers of patients
in the study groups to questions in the postoperative period, we noted a positive dynamics in the evaluation of quality of life during the observation period in both groups (Table 3). Patients of both study groups noted that it became easier to drive a car \( (P<0.01) \), and less feeling fatigue or strain in the eyes \( (P=0.0004 \text{ and } P=0.002, \text{ respectively}) \). Patients in the ReLEx SMILE group 6 months after the correction were more satisfied with visual quality compared to patients in the Femto-LASIK group, which is particularly reflected in the answers to question 4 after 6 months \( (P=0.0003) \).

Six months after the surgery, more than 90% of respondents were satisfied with the visual acuity and quality of vision achieved. Notably, difficulties while driving a car at night were experienced in the ReLEx SMILE group by only two persons (3.6%) and in the Femto-LASIK group by four persons (6.4%).

The QIRC provided an evaluation of patient’s anxiety, the less anxious a patient is, the higher the score. An analysis of the answers to the questionnaire questions 8–10 and 13 characterizing the patients’ concern about their eye protection from ultraviolet radiation and possible financial losses, showed that before the operation the level of anxiety in the groups was the same \( (P=0.23) \) (Table 3). So in questions 8–9 concerning the cost of the initial and additional refractive surgery, an overwhelming number of respondents answered “Not at all” and “A little bit”. The answers to question 10 showed the same level \( (P>0.05) \) depending on glasses and contact lenses used. After refractive surgery, the
respondents did not need an additional correction, and in this connection they did not answer question 7. It is worth noting that patients of the ReLex SMILE group are to a lesser extent (P<0.0001) concerned with medical complications of laser correction (question 12). This result can be explained by the technologic advantages of ReLex SMILE. At the same time, patients after the ReLex SMILE during the early postoperative period (1 month) were more concerned (P<0.01) about the quality of vision compared with the Femto-LASIK group (question 11). This trend correlates with the dynamics of the recovery of the UCVA (Table 2). As for the respondents in the Femto-LASIK group, there is a decrease in the level of anxiety about possible medical complications from month to month (P=0.001, P=0.0002 and P<0.0001).

An analysis of Femto-LASIK group’s answers to the “emotional well being” block questions (14–20) revealed the following: it was dominated by people who were unhappy with their appearance (P<0.0001) (question 14). In the SMILE group, there were people who were self-confident, feeling attractive, and apparently they went for vision correction more likely to improve their vision, increase convenience in everyday life, and not because of low self-esteem. Despite their great self-confidence, patients from the SMILE group were initially more dissatisfied with being unable to deal with the cases they would like (question 19) (P=0.003) and had a stronger desire to try something new (question 20) (P=0.02). After refractive surgery, the self-esteem of Femto-LASIK patients increased and remained high for all 6 months (P<0.0001). They began to receive compliments more often (P=0.03). As for the SMILE group, its participants noted that they became more self-confident and more happy 1 month after the operation (P<0.0001).

It is important to note that in general, the patients of the SMILE group (P<0.01) and the Femto-LASIK group (P<0.01) felt statistically significantly more comfortable compared to preoperative data, starting from the first month. Given all the data received, the answers to the 20-item QIRC Questionnaire (Table 3), it can be concluded that the groups “Femto-LASIK” and “SMILE” were initially comparable in terms of QoL (P>0.05). After laser correction of complex myopic astigmatism using Femto-LASIK and ReLex SMILE methods, the overall QoL indicators are statistically significant (P<0.01) exceeding preoperative data (Figure 3).

Change of average score representing the patients’ answers to the questions of the QIRC questionnaire in study groups over the follow up after the operation is reaching the maximum values by the end of the observation period (P<0.001) (Figure 3).

**Discussion**

This study has demonstrated that although patients in both treatment groups achieved desired refractive correction following surgery, there is a paucity in the literature regarding QoL measures following refractive correction surgery, particularly following ReLex SMILE. The US Food and Drug Administration (FDA) collaborated with the National Eye Institute and the Department of Defense to develop an online questionnaire, Patient-Reported Outcomes with LASIK (PROWL) survey, to assess functional limitations and patient satisfaction after LASIK surgery. They found that patient-rated satisfaction at 3 and 6 months was greater than 90%, with 1%-2% of patients reporting dissatisfaction after surgery.

Notably, the authors report that the questionnaire may be relevant for the assessment of visual symptoms in clinical trials, including for FDA approval, and it might not be practical for use by surgeons to assess individual patient outcomes. Additionally, it did not address the more qualitative aspects of QoL, such as anxiety and happiness, as we have in the current study.

A study from Lesueur et al investigated predictors of QoL related to PRK, LASIK, and phakic IOL refractive procedures. They found that those patients with higher degrees of myopia had significant improvements in self-esteem and coping as compared to other patients. They found that quality of vision was directly correlated with improvement of QoL, satisfaction scores, and BCVA preoperatively and postoperatively in all patients, but interestingly no correlation was noted between visual acuity and patient satisfaction.

Katzen published a paper in 2002 related to the anxiety of patients undergoing laser refractive surgery, noting that as refractive surgery has rapidly evolved and the quest to obtain faster visual recovery, fewer complications, and early stability continues, there is little in the literature that addresses the anxiety experienced by most refractive surgical patients. Unfortunately in the 16 years since that publication, minimal steps have been taken to further study the anxiety and management of anxiety or fears in refractive surgery patients.

As a result of laser correction, the study group patients gave us comparable visual results, as no complications occurred in either group and refractive results were within ±1.0 D for all eyes. Contrary to our expectations, despite technologic advantages of ReLex SMILE technique, general anxiety...
Table 3 Answers of the patients in the study groups to the questions of the QIRC questionnaire (mean±SD; n=number of patients/eyes)

<table>
<thead>
<tr>
<th>No</th>
<th>Question</th>
<th>Observation time period</th>
<th>Preoperative Femto-LASIK n=62</th>
<th>Preoperative SMILE n=56</th>
<th>Comparison between groups</th>
<th>1 month Femto-LASIK n=62</th>
<th>1 month SMILE n=56</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>How much difficulty do you have driving in glare conditions?</td>
<td></td>
<td>40.82±13.85</td>
<td>38.59±12.26</td>
<td></td>
<td>38.52±9.84</td>
<td>36.27±10.37</td>
</tr>
<tr>
<td>2</td>
<td>During the past month, how often have you experienced your eyes feeling tired or strained?</td>
<td></td>
<td>45.42±10.15</td>
<td>44.14±10.39</td>
<td></td>
<td>44.43±9.67</td>
<td>45.65±10.04</td>
</tr>
<tr>
<td>3</td>
<td>How much trouble is not being able to use off-the-shelf (nonprescription) sunglasses?</td>
<td></td>
<td>36.95±12.34</td>
<td>42.66±14.34</td>
<td>*</td>
<td>38.43±13.79</td>
<td>41.55±11.81</td>
</tr>
<tr>
<td>4</td>
<td>How much trouble is having to think about your spectacles or contact lenses or your eyes after refractive surgery before doing things; eg, traveling, sport, going swimming?</td>
<td></td>
<td>41.84±13.43</td>
<td>38.47±12.84</td>
<td></td>
<td>44.86±11.67</td>
<td>43.71±12.65*</td>
</tr>
<tr>
<td>5</td>
<td>How much trouble is not being able to see when you wake up, eg, to go to the bathroom, look after a baby, see alarm clock?</td>
<td></td>
<td>50.53±11.25</td>
<td>42.26±14.34</td>
<td>*</td>
<td>52.97±9.21</td>
<td>46.79±13.57</td>
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<tr>
<td>6</td>
<td>How much trouble is not being able to see when you are on the beach or swimming in the sea or pool, because you do these activities without spectacles or contact lenses?</td>
<td></td>
<td>52.51±11.93</td>
<td>45.08±13.7</td>
<td>*</td>
<td>60.29±8.51***</td>
<td>52.77±14.21**</td>
</tr>
<tr>
<td>7</td>
<td>How much trouble is your spectacles or contact lenses when you wear them when using a gym/doing keep-fit classes/circuit training etc?</td>
<td></td>
<td>42.62±13.77</td>
<td>35.39±13.97</td>
<td>*</td>
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<tr>
<td>8</td>
<td>How concerned are you about the initial and ongoing cost to buy your current spectacles/contact lenses/refractive surgery?</td>
<td></td>
<td>53.02±11.71</td>
<td>52.85±9.32</td>
<td></td>
<td>56.89±9.86</td>
<td>58.36±10.52**</td>
</tr>
<tr>
<td>9</td>
<td>How concerned are you about the cost of unscheduled maintenance of your spectacles/contact lenses/refractive surgery; eg, breakage, loss, new eye problems?</td>
<td></td>
<td>49.68±12.65</td>
<td>49.58±13.36</td>
<td></td>
<td>45.2±11.92</td>
<td>45.18±12.26</td>
</tr>
<tr>
<td>10</td>
<td>How concerned are you about having to increasingly rely on your spectacles or contact lenses since you started to wear them?</td>
<td></td>
<td>48.98±13.34</td>
<td>46.54±13.1</td>
<td></td>
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<tr>
<td>11</td>
<td>How concerned are you about your vision not being as good as it could be?</td>
<td></td>
<td>44.05±12.33</td>
<td>37.5±9.64</td>
<td>*</td>
<td>55.53±12.01****</td>
<td>47.23±13.2****</td>
</tr>
<tr>
<td>12</td>
<td>How concerned are you about medical complications from your choice of optical correction (spectacles, contact lenses, and/or refractive surgery)?</td>
<td></td>
<td>37.57±13</td>
<td>49.5±13.32</td>
<td>*</td>
<td>45.07±13.9****</td>
<td>44.59±12.13*</td>
</tr>
<tr>
<td>13</td>
<td>How concerned are you about eye protection from ultraviolet radiation?</td>
<td></td>
<td>48.06±12.94</td>
<td>49.6±13.78</td>
<td></td>
<td>50.16±12.89</td>
<td>49.48±11.39</td>
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<tr>
<td>14</td>
<td>During the past month, how much of the time have you felt that you have looked your best?</td>
<td></td>
<td>32.41±11.43</td>
<td>46.3±16.81</td>
<td>*</td>
<td>49.48±18.28****</td>
<td>53.27±19.56*</td>
</tr>
<tr>
<td>15</td>
<td>During the past month, how much of the time have you felt that you think others see you the way you would like them to (eg, intelligent, sophisticated, successful, cool, and so on)</td>
<td></td>
<td>43.04±12.43</td>
<td>43.7±12.49</td>
<td></td>
<td>45.06±15.47</td>
<td>49.2±17.83*</td>
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Table 3

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<tr>
<th>Comparison between groups</th>
<th>Femto-LASIK n=62</th>
<th>SMILE n=56</th>
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<td></td>
<td>45.06±13.11</td>
<td>40.82±12.00</td>
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<td>47.31±14.07**</td>
<td>47.64±14.37**</td>
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<td></td>
<td>50.16±8.38**</td>
<td>48.78±13.85*</td>
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<td></td>
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<td></td>
<td>56.89±10.11</td>
<td>62.68±7.6****</td>
<td></td>
<td>57.59±7.81*</td>
<td>62.04±8.72**</td>
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<td></td>
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<td>56.36±11.25*****</td>
<td>59.52±7.55*****</td>
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<td>57.70±11.58****</td>
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(Continued)
level did not differ in both groups. It should be noted that 1 month after surgery, patients of both groups under study experienced a significantly higher level ($P<0.01$) of anxiety than in the long-term postoperative period (6 months). In our opinion, this determines the need for psychological support from the surgeon during this period. It is worth noting positive dynamics in both groups within a month after the operation in the fall of anxiety level due to vision ($P<0.0001$).

All the patients equally felt certain fears, especially in the first months after surgery: the fear to lose the reached vision acuity, the fear of possible complications and financial losses. This observation provides some explanation regarding fears or stress that a patient may experience that the physician can be aware of and offer assistance or advice. We found more interesting facts in the course of analyzing the answers to the “emotional well being” block questions (14–20). A significant variation of answers to certain questions draws attention.

The authors speculate whether the different physical qualities of the procedures themselves may influence the differences in QoL results and timing of results. ReLex SMILE and Femto-LASIK procedures have variable degrees of trauma to the tissue, ocular shape transformation due to surgery, and corneal drought. Other contributing factors may be related to the time duration of surgery, recovery time needed, and postoperative management protocol. All of these factors are planned to be investigated in future studies.

Evaluation and measurement of the patients’ QoL, based on the questionnaire represents important additional information and conclusions related to patient satisfaction and expectations that cannot be determined from visual acuity and refractive status alone. QoL assessment provides evaluation of the emotional condition of patients and may allow for an individual approach to the patient management in pre- and postoperative periods.

## Conclusion

This study focused on addressing patients’ satisfaction and QoL following vision-correcting ReLex SMILE and Femto-LASIK surgeries. In addition to traditional objective measurements of visual acuity and ophthalmic examination, the patient experience was evaluated using a QoL questionnaire. Results of the study confirm a positive visual acuity outcome in both procedures with a lower level of anxiety. There were no significant differences between SMILE and Femto-LASIK in terms of QoL improvement, indicating that both procedures are effective in improving patients' QoL in the long term.
come after treatment regardless of the surgical technique implemented. Improvements in QoL can be appreciated as early as the first day following surgery.

However, it is apparent that patients usually need some time to adapt to the new vision conditions and how these changes impact their daily lives as maximum QoL improvement was not achieved until later in the observation period. Long-term results from the study demonstrated high patient satisfaction with both methods. However, our findings revealed a higher satisfaction trend in QoL in those who received the ReLEx SMILE refractive correction.

As patient satisfaction is key in vision-correcting surgery, the addition of QoL assessment to traditional ophthalmic assessments offers a more detailed evaluation of patient outcomes. We recommend that QoL be included as best practice in the postoperative period to assess the results after corrective surgery.

**Author contributions**

All authors contributed toward data analysis, drafting and revising the paper, gave approval for the final version to be published and agree to be accountable for all aspects of the work.

**Disclosure**

The authors report no conflicts of interest in this work.

**References**


