

SMILE – characteristics of the procedure and the patients' quality of life

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HIGHLIGHTS

ReLEx® SMILE has a positive effect on the patients' quality of life.

ABSTRACT

ReLEx® SMILE is a relatively new flapless laser vision correction procedure carried out exclusively by femtosecond laser which earned confidence among both physicians as well as patients. The procedure constitutes an alternative to LASIK, which was considered so far the golden standard in myopia and myopic astigmatism corrections. The present paper discusses the advantages of the ReLEx® SMILE in comparison with other types of laser vision correction, including the patients quality of life after ReLEx® SMILE.

Key words: ReLEx® SMILE, laser vision correction, quality of life

INTRODUCTION

Refractive surgery is one of the most rapidly growing subspecialties of ophthalmology. ReLEx[®] SMILE (Refractive Lenticule Extraction, Small Incision Lenticule Extraction) – a relatively new, third-generation laser vision correction procedure – has recently become increasingly popular. Unlike LASIK and other lamellar laser vision correction procedures, ReLEx[®] SMILE is performed only with one, femtosecond laser [1]. Reshaping the corneal curvature is performed in an innovative "endoscopic" way – the femtosecond laser separates a lenticule in the corneal stroma, which is then removed through a small side-cut, 2–5-mm incision (fig. 1) [2].

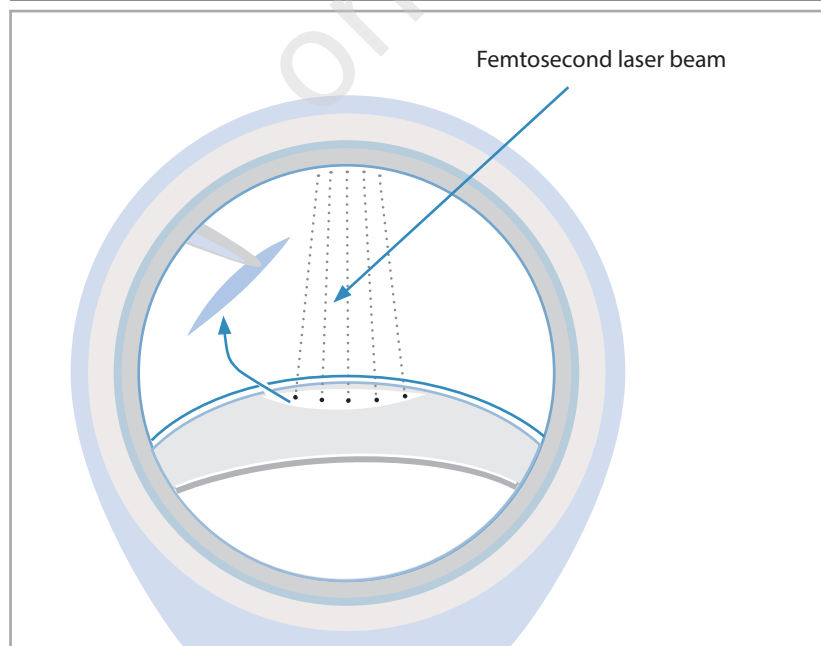
The total laser treatment time is about 30 s, regardless of the refractive error size [2], but the shape and the size of the intraocular microlens correspond to the value of the refractive error. Compared to LASIK and other lamellar procedures, ReLEx[®] SMILE is a minimally invasive treatment since there is no flap creation, photoablation, and the anterior stroma and corneal nerves are left intact. This is also reflected in many important aspects of the postoperative period, such as minimal postoperative inflammation or less effect on corneal biomechanics. Currently, ReLEx[®] SMILE is used only for correction of myopia and myopic astigmatism. Myopia can be corrected to -10 D and myopic astigmatism to -5 D [2]. Correction of hyperopia with ReLEx[®] SMILE is still being researched. In 2016, ReLEx[®] SMILE was approved by the U.S. Food and Drug Administration (FDA) and has since been available worldwide [3].

Visual acuity (VA) is the basic parameter evaluated after refractive surgery. Objective ReLEx[®] SMILE outcomes such as VA efficacy, predictability, stability and safety are satisfactory and at least comparable to LASIK, which until now has been considered the gold standard for the permanent correction of myopia and myopic astigmatism [4]. Yan et al. reported no significant differences in efficacy, predictability, or safety between ReLEx[®] SMILE and FemtoLASIK (femtosecond laser-assisted in situ keratomileusis) [5]. However, Ganesh et al. found greater predictability of ReLEx[®] SMILE compared to FemtoLASIK [6]. Moreover, refractive results for the correction of low myopia with ReLEx[®] SMILE are at least comparable to those obtained after lamellar photorefractive keratectomy (PRK) or laser subepithelial keratomileusis (LASEK) [7].

In the recent years, LVC procedures have become more popular and available in Poland, particularly among young, healthy, and professionally active people who want to improve their quality of life – QoL (e.g., playing sports, travelling, or developing their career by freeing themselves from glasses or contact lenses). Evaluation of laser vision correction (LVC) results should involve patients' subjective feelings and subjective assessment of their quality of vision and QoL. Many studies have shown that patient's own subjective assessment may differ from the their physicians and psychologists diagnoses [8, 9]. This study aimed to present the advantages of ReLEx[®] SMILE compared to other LVC laser procedures and to discuss changes in patients' QoL following ReLEx[®] SMILE.

FIGURE 1

ReLEx[®] SMILE procedure technique.



RELEX® SMILE – ONLY WITH FEMTOSECOND LASER

The minimally invasive, flap-free ReLEx® SMILE is performed only with a femtosecond laser, which is less sensitive than an excimer laser to external factors, such as room temperature and humidity [10, 11]. Moreover, femtosecond laser in ReLEx® SMILE requires significantly less energy compared to excimer LVC procedures. Another advantage of ReLEx® SMILE is that there is no corneal ablation [12]. Due to the benefits of the femtosecond laser, ReLEx® SMILE is a more predictable and precise procedure that limits the amount of ocular inflammation and provides quicker corneal recovery [10]. Thanks to the use of only one laser platform, the time of the procedure is shorter compared to FemtoLASIK – an important factor for both the surgeon and the patient.

CORNEAL BIOMECHANICS

Corneal biomechanics is very important after LVC procedures. Structural elements of the cornea and their organization affect corneal biomechanical parameters, such as elasticity and stiffness. A better understanding of corneal biomechanics after LVC, including ReLEx® SMILE, aims to improve safety, efficacy and predictability of LVC procedures. The corneal stroma comprises 90% of the corneal thickness. The cohesive tensile strength of the anterior corneal stroma, which makes up 40% of its thickness, is by at least 50% greater than the posterior stroma [13]. ReLEx® SMILE is a flap-free procedure that, unlike previous generation treatments, leaves Bowman's membrane and anterior corneal stroma intact. Therefore, ReLEx® SMILE has a positive effect on corneal biomechanics.

Reinstein et al. created a mathematical model to compare tensile strength of the cornea after PRK, LASIK, and ReLEx® SMILE [14]. They found that the total stromal tensile strength was considerably higher after ReLEx® SMILE than PRK and LASIK in the treatment of the same size refractive error. For example, in a 550- μm cornea after 100- μm tissue removal, postoperative total stromal tensile strength (TTS) was 75% for ReLEx® SMILE, 68% for PRK, and 54% for LASIK. Therefore, these authors postulated that ReLEx® SMILE should be the preferred technique for laser correction of high myopias.

Another parameters to assess the biomechanical strength of the cornea are corneal hysteresis (CH, corneal hysteresis) and corneal resistance factor (CRF, corneal resistance factor). In an *in vivo* study, Wang et al. observed a decrease in CH and CRF after ReLEx® SMILE compared to FemtoLASIK when treating high myopias above -6 D, but no significant differences were observed for lower myopias [15]. Wu et al. reported a statistically significant advantage of ReLEx® SMILE over FemtoLASIK [16], and Dou et al. over

the classic LASEK in terms of CH and CRF [17]. However, Agca et al. found no significant differences between ReLEx® SMILE and FemtoLASIK [18]. Reinstein et al. concluded that it is highly likely that ReLEx® SMILE provides greater protection of corneal biomechanical stability than LASIK; however, this has not been confirmed due to technological limitations [2]. Moreover, in ReLEx® SMILE, anterior stroma, the strongest region of the cornea, remains intact, which, in the long-term follow-up, should translate into a lower risk of refractive error regression and developing corneal ectasia [19].

HIGHER-ORDER ABERRATIONS

Laser vision correction procedures induce postoperative higher-order aberrations (HOAs) such as coma, trefoil, or spherical aberration, which contribute to postoperative night and twilight vision problems or reduced contrast sensitivity [20]. Therefore, HOAs may lead to decreased quality of vision and QoL. Authors of a comparative study found no significant difference in the severity of HOAs between ReLEx® SMILE and wavefront FemtoLASIK – the most recommended method of refractive error correction in eyes with HOAs [21]. However, Ganesh et al. [6] and Lin et al. [22] reported a statistically significantly lower incidence of HOAs after ReLEx® SMILE compared to FemtoLASIK. Moreover, a lower prevalence of HOAs after correction of high myopia was observed at one-year follow-up after ReLEx® SMILE compared to lamellar LASEK [23]. However, Pedersen et al. observed a decrease in HOAs several years after LASEK, which may be related to corneal epithelial remodeling [24].

CORNEAL INFLAMMATION AND HEALING

Corneal and ocular surface wound healing are of great importance as they can affect LVC safety, efficacy, and predictability. Disturbed healing process and inflammation can lead to undercorrection, overcorrection, or refractive error regression [25, 26], postoperative corneal haze, severe dry eye symptoms, or biomechanical instability of the cornea [27]. Gao et al. found that in the early postoperative period, ReLEx® SMILE resulted in milder ocular surface changes than FemtoLASIK [28]. Moreover, in ReLEx® SMILE group IL-6 and NGF levels in tears were lower and recovered faster. Dong et al., in a study in rabbits, found that ReLEx® SMILE induces less apoptosis, keratocyte proliferation, and inflammation compared to FemtoLASIK [27]. These authors hypothesize that minimally invasive ReLEx® SMILE induces less corneal trauma due to a smaller incision and no photoablation, both associated with reduced chemokine expression and less necrotic debris in the interface. Fur-

thermore, leaving Bowman's membrane intact and no need for creating the corneal flap reduces corneal exposure to inflammatory cytokines.

DAMAGE TO CORNEAL NERVES

The cornea is one of the most densely innervated tissues in the human body [29]. Corneal nerve fibers are prone to damage during LVC procedures [30]. Compared to other LVC procedures ReLEx® SMILE leaves the anterior part of the cornea untouched except for a small incision made to remove the lenticule. However, in lamellar LVC procedures excimer laser photoablation damages the anterior part of the cornea, and in LASIK, nerve fibers are even further damaged during corneal flap creation with a mechanical microkeratome or a femtosecond laser.

Compared to other LVC procedures, minimally invasive ReLEx® SMILE causes less damage to corneal nerve fibers and minimizes corneal sensation, particularly in the first months after surgery [28, 31], which reduces the risk of neurotrophic epitheliopathy and dry eye syndrome (DES). Donnenfeld et al. found a positive correlation between corneal denervation and DES [32].

DRY EYE DISEASE

Temporary postoperative dry eye symptoms are the most common complication occurring after LVC procedures [33]. Functional and morphological changes in ocular cells contribute to the dry eye [34], but damage to nerves supplying the cornea and ocular surface inflammation play a major role in the development of symptoms. The subjective symptoms of iatrogenic dry eye disease are the same as in the case of classic dry eye disease. In the postoperative period, due to corneal neurotrophic keratopathy, patients complain of vision fluctuations throughout the day and deterioration of night and evening vision. Dry eye symptoms may not only negatively affect the quality of vision, but they can also make it difficult to perform daily activities, thereby reducing patients' QoL [35, 36] and negatively affecting their physical, mental, and social wellbeing [37].

Therefore, diagnosis should involve physical examination, individual assessment of patients' feelings and postoperative problems, as well as impact of dry eye symptoms on patients' daily life. ReLEx® SMILE is a minimally invasive procedure, which means that it causes less damage to the corneal nerves and less surface inflammation. Therefore, the objective symptoms characterizing dry eye (Schirmer test, T-BUT) are milder after ReLEx® SMILE compared to FemtoLASIK [38–40]. Moreover, Shen et al. found in their meta-analysis that patients after LASIK experienced more severe dry eye symptoms compared to patients after ReLEx® SMILE [39].

The most widely used therapy for dry eye disease is tear substitution with preservative-free formulations, which are routinely recommended after LVC procedures. First-line treatment involves regular use of artificial tears, which can be inconvenient, limit daily functioning, generate further costs, thus reducing quality of life.

In a study by Denoyer et al., 80% of ReLEx® SMILE patients compared to 57% of FemtoLASIK patients did not use artificial tears 6 months after treatment [41]. The remaining ReLEx® SMILE patients applied artificial tears significantly less frequently (occasionally or up to 3 times a day) compared to FemtoLASIK patients. Moreover, none of the patients in the ReLEx® SMILE group needed to use gels.

RELEX® SMILE COMPLICATIONS

ReLEx® SMILE, compared to other LVC procedures, is technically more challenging and has a steeper surgeon learning curve [2]. Nevertheless, it is a safe procedure with a low risk of intraoperative and postoperative complications [2]. The undisputed advantage of ReLEx® SMILE is no risk of corneal flap complications such as (but not limited to) corneal flap tear, flap detachment or wrinkling, or its dislocation following trauma. For this reason, ReLEx® SMILE is a LVC treatment suitable for athletes.

INTRAOPERATIVE PATIENT EXPERIENCE

Perioperative safety and comfort influence satisfaction of patients who undergo LVC procedures. Intraoperative experiences during ReLEx® SMILE and FemtoLASIK are similar [42]. However, despite replacing mechanical microkeratome with a femtosecond laser LASIK patients experience more anxiety and fear during the first stages of the procedure (microkeratome suction, flap fabrication and lifting) compared to ReLEx® SMILE patients [42].

PATIENTS' QUALITY OF LIFE

Quality of life (QoL) is a very complex, multifaceted concept that reflects many aspects of human life. In the 1990s, Schipper et al. introduced the term health-related quality of life (HRQoL) understood as the "functional effect of disease and its treatment, as perceived by the patient" [43]. It means that patients assess the effectiveness of therapeutic procedures and the disease itself on physical, psychological and social levels.

Questionnaires are basic tools used to assess patients' QoL. Validated questionnaires such as the Quality of Life Impact of Refractive Correction (QIRC), the National Eye Institute Refractive Quality of Life (NEI-RQL), or the Refractive Status Vision Profile (RSVP) can be used to assess patients' QoL after refractive surgery [44].

QIRC is the most commonly used questionnaire to assess patients' QoL. It has good reliability and involves many questions about patients' visual function, ocular symptoms, daily functioning, costs, health concerns and well-being [44]. Studies conducted using the QIRC questionnaire demonstrate that LVC procedures, including ReLEx® SMILE, improve patients' QoL on multiple levels. In a study conducted by Klokova et al. patients completed QIRC questionnaires preoperatively and at 1, 3, and 6 months following ReLEx® SMILE and FemtoLASIK [45]. At each follow-up visit, improved QoL was reported in both treatment groups, reaching the maximum values at the end of the observation. Moreover, at each follow-up visit, QoL significantly exceeded preoperative values, and at the third and fourth follow-up visits, patients after ReLEx® SMILE reported significantly higher QoL compared to patients after FemtoLASIK.

However, in a study conducted in Singapore no significant difference in QoL was reported in terms of physical and mental functioning after ReLEx® SMILE and FemtoLASIK [42]. Moreover, Ang et al., who examined patients with low and moderate-to-high myopia, found no difference in patient-reported QoL after ReLEx® SMILE [46].

The positive effect of ReLEx® SMILE on patients' QoL has also been reported several years after the treatment. Four years after ReLEx® SMILE procedure, the mean total patient-reported QoL was significantly higher compared to spectacle wearers [47]. In another study, patients' QoL was similar 3 years after ReLEx® SMILE and FemtoLASIK, although dry eye symptoms and glare were less frequent in ReLEx® SMILE patients [48].

TWILIGHT AND NIGHT VISION PROBLEMS

Night and twilight vision problems influence patients' satisfaction with LVC procedures and their subjective assessment of QoL and quality of vision. Such complications may occur even after a simple laser refractive procedure. There are several forms of low-light vision problems: starburst, halo, glare, ghosting, and reduced contrast sensitivity. Problems with twilight and night vision can impair quality of vision and limit daily functioning, such driving a car, riding a bike, or performing other basic activities in the evenings and during the fall and winter months. It should be noted that these symptoms are subjectively perceived [49]. Ang et al. [42, 46] and Damgaard et al. [50] conducted studies on halo and glare effects after ReLEx® SMILE. Their incidence and severity were assessed 1 and 3 months following treatment using the same questionnaire with a 5-point scale (1 meaning no halo/glare effect and 5 meaning very/extremely severe halo/glare effect). Ang et al. reported that the severity of halo and glare in the first month after surgery was 2.3 ± 1.3 and 2.3 ± 1.0 , respectively, but in the

third month it decreased to 1.8 ± 0.9 and 1.77 ± 0.8 , respectively [42]. In their subsequent study they evaluated halo and glare in two groups of patients with low and moderate/high myopia [46]. The severity of halo and glare effects did not differ significantly between the groups. Moreover, their intensity, like in the previous study, decreased over time. Damgaard et al. studied halo and glare effects in patients treated for myopia and myopic astigmatism who underwent ReLEx® SMILE in 1 eye and FemtoLASIK in the contralateral eye [50]. Both procedures were performed on the same day. At the 3rd-month follow-up we reported less halo and glare in both eyes and no significant difference in their severity between treatments. Ganesh et al., 15 days after ReLEx® SMILE and LASIK, evaluated on a 4-point scale (0 – no difficulty, 4 – severe difficulty) the effect of glare from the headlights of oncoming vehicles on the visibility of road signs [6]. Glare effect was significantly less severe after ReLEx® SMILE compared to LASIK ($p < 0.001$). Three years after procedure, the glare effect rated on a scale of 0 to 10 (0 – no effect; 10 – maximum severity) was significantly less severe after ReLEx® SMILE compared to FemtoLASIK ($p = 0.021$) [48].

PATIENT SATISFACTION WITH RELEX® SMILE

ReLEx® SMILE patients report significant vision improvement and are highly satisfied with the procedure [51–53]. A study by Ivarsen et al. conducted in a group of 922 patients in the third month after ReLEx® SMILE deserves a special mention [54]. The mean score of patients' satisfaction evaluated on a scale from 0 to 10 (with 10 being the highest level of satisfaction) was 9.34. Only 6 patients were dissatisfied (score below 5), but after additional treatment, at the one-year follow-up, this number was lower (2).

Vestergaard et al. reported that in the third month after ReLEx® SMILE the mean satisfaction level rated on a scale of 0 to 10 (with 10 being the maximum satisfaction level) was 9.3 ± 1.1 . Almost all patients (95%) reported significant vision improvement, 4% moderate, and 1% little or no improvement [53]. In the study by Sekunda, 6 months following ReLEx® SMILE, the values were 68.2%, 28.4%, and 3.4%, respectively [51]. The high level of patients' satisfaction is confirmed by their willingness to recommend it to their friends and relatives. Vestergaard et al. reported that 95% (89) of their patients recommended ReLEx® SMILE to their friends [53], whereas in a study by Sekunda, 93.3% (45) of respondents declared that they would choose this procedure again in the future [51].

CONCLUSIONS

ReLEx® SMILE, similarly to other laser vision correction procedures, positively impacts patients' QoL. Due to in-

novative technology, both patients and refractive surgeons will find ReLEx® SMILE a very attractive method for the correction of myopia and myopic astigmatism.

Figures: from the author's own materials.

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Authors' contributions:

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Conflict of interest:

None.

Financial support:

None.

Ethics:

The content presented in the article complies with the principles of the Helsinki Declaration, EU directives and harmonized requirements for biomedical journals.