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Systemic contraindications for laser vision correction surgery

Przeciwwskazania ogólne do zabiegów laserowej korekcji wzroku

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Abstract

Introduction: Laser refractive surgery corrects refractive errors by changing the shape of the anterior surface of the cornea and its refractive power by using a laser. Patients with refractive errors and systemic comorbidities pose a challenge for refractive surgeons. According to the guidelines of ophthalmological societies, the coexistence of autoimmune connective tissue diseases or hormonal disorders, some pharmacotherapies, pregnancy and lactation are contraindications for refractive procedures. These recommendations have been formulated on the basis of case reports or recommendations coming from other ophthalmic surgeries. **Aim:** The aim of the study was to summarise the current literature data on systemic contraindications for laser vision correction. **Materials and methods:** The literature review included the PubMed database. In the search for relevant articles, the following keywords were used: "refractive surgery", "contraindications", "LASIK", "PRK", "laser in situ keratomileusis", "photorefractive keratectomy". The references of articles that met the criteria were also analysed. **Discussion:** The main reason for considering some systemic conditions and pharmacotherapy as exclusion criteria for refractive surgery was the concern of an increased risk of postoperative eye inflammation, unpredictable healing and corneal remodelling, as well as a severe dry eye syndrome. In recent decades, a number of articles have been published supporting the safety profile of refractive procedures in patients with inactive autoimmune diseases, well-controlled diabetes or undergoing specific pharmacotherapy. These publications were based on either retrospective studies or case series, with short-term follow-up and their results should be interpreted with caution. **Conclusions:** Active or uncontrolled autoimmune diseases, pregnancy and lactation are absolute contraindications for laser vision correction. The decision to perform refractive surgery in patients with inactive and well-controlled systemic diseases or risk factors should be made individually and carefully by an experienced surgeon.

Keywords: refractive surgery, contraindications, LASIK, PRK, laser in situ keratomileusis, photorefractive keratectomy

Streszczenie

Wstęp: Laserowa chirurgia refrakcyjna to chirurgia rogówki korygująca wady refrakcji poprzez zmianę kształtu przedniej powierzchni rogówki i jej siły łamiącej przy użyciu lasera. Pacjenci z wadą wzroku i współistniejącymi chorobami ogólnymi stanowią szczególne wyzwanie dla chirurgów refrakcyjnych. Według wytycznych towarzystw okulistycznych do przeciwwskazań do zabiegów laserowej korekcji wzroku należą współistnienie autoimmunologicznych chorób tkanki łącznej czy zaburzeń hormonalnych, a ponadto stosowanie niektórych leków, ciąża i karmienie piersią. Zalecenia te zostały sformułowane na podstawie opisów przypadków lub rekomendacji opracowanych w odniesieniu do innych zabiegów okulistycznych. **Cel:** Celem pracy jest podsumowanie aktualnych danych literaturowych na temat ogólnych przeciwwskazań do laserowej korekcji wzroku. **Materiał i metody:** Przegląd piśmiennictwa obejmował bazę PubMed. W poszukiwaniu odpowiednich artykułów wykorzystano następujące słowa kluczowe: „chirurgia refrakcyjna", „przeciwwskazania", „LASIK", „PRK", „laser *in situ keratomileusis*", „keratektomia fotorefrakcyjna". Przeanalizowano także piśmiennictwo dołączone do spełniających kryteria artykułów. **Omówienie:** Głównym powodem uznania niektórych schorzeń ogólnych i farmakoterapii za kryteria wykluczające możliwość wykonania zabiegu korekcji wzroku była obawa przed zwiększonym ryzykiem reakcji zapalnej ze strony oka, nieprzewidywalności procesów gojenia i przebudowy rogówki czy rozwoju ciężkiego zespołu suchego oka. W ostatnich dekadach opublikowano wiele prac potwierdzających bezpieczeństwo zabiegów refrakcyjnych u osób z nieaktywnymi chorobami autoimmunologicznymi, z dobrze kontrolowaną cukrzycą czy stosujących niektóre leki. Publikacje te miały charakter badań retrospektywnych lub opisów serii przypadków, dotyczyły krótkiego okresu obserwacji i ich wyniki należy interpretować ostrożnie. **Wnioski:** Aktywne lub niekontrolowane choroby autoimmunologiczne, ciąża i okres karmienia stanowią bezwzględne przeciwwskazania do zabiegów laserowej korekcji wzroku. Decyzja o zabiegu refrakcyjnym u pacjentów z nieaktywnymi i właściwie kontrolowanymi chorobami ogólnymi lub czynnikami ryzyka powinna być podjęta indywidualnie i z rozwagą przez doświadczonego chirurga.

Słowa kluczowe: chirurgia refrakcyjna, przeciwwskazania, LASIK, PRK, laser *in situ keratomileusis*, keratektomia fotorefrakcyjna

INTRODUCTION

Uncorrected refractive errors are one of the leading causes of visual impairment worldwide[1]. About 25–30% of Europeans and Americans suffer from myopia, whereas this percentage reaches up to 80–90% among Asian children and adolescents[2]. Hyperopia affects about 10% of the population, while almost 1/3 of US population suffer from significant astigmatism. Presbyopia, i.e. progressive inability to focus on near objects, resulting from either reduced or lost accommodation after the age of 40 years, affects over 2 billion people globally. The epidemic of refractive errors is further promoted by the digitisation of life, the accompanying accommodation effort and the progressive aging of societies. It is predicted that by 2050, one in two Europeans and Americans will be myopic[1]. Refractive corneal surgery has been a modern alternative to corrective glasses and contact lenses for over three decades. Laser vision correction (LVC) is one of the most frequently performed surgical procedures globally, with approximately 5 million LVCs performed each year (approximately 1 million in Europe) and a continuous upward trend in this area – by approximately 4–7.5% annually. The largest increase in the number of procedures is observed in Europe, Asia, the United States and Latin America. In Poland, LVCs are performed in over 50 ophthalmological centres and it is estimated that tens of thousands of them are performed each year. Correction of myopia and myopic astigmatism accounts for over 80% of these procedures[3].

The continuous increase in the popularity of LVCs results from the very high efficiency and safety of refractive procedures, the growing social expectations in terms of quality of life and vision, especially in highly developed countries, where seniors are more active, and finally occupational visual standards. Refractive corneal surgery is one of the safer ophthalmic procedures. Safety criteria must be met to qualify for the procedure. However, the vast majority of patients interested in visual correction meet the eligibility criteria. These procedures are not performed in persons under the age of 18 years, and there is no upper age limit; ocular comorbidities, certain general diseases, pregnancy and breastfeeding are the main contraindications.

The cornea is the strongest optical element of the eye, generating about 60% of its refractive power. Transparency and lack of vascularisation are its characteristic features. The corneal stroma, which represents about 90% of the total corneal thickness, consists of an extracellular matrix containing collagen fibres that form lamellae, with keratocytes arranged between them.

Laser refractive surgery is a corneal surgery that corrects refractive errors by changing the shape of the anterior corneal surface and its bending strength using excimer and/or femtosecond lasers. Laser modelling of the corneal curvature results in corneal flattening in the centre in the case of myopia or achieving a convex shape of the paraxial and central cornea in the case of hyperopia. The mechanism of an excimer (argon-fluoride) 193 nm wavelength laser is based on pulsed emission of ultraviolet (UV) radiation, strongly absorbed by the cornea. Then, the bonds between carbon atoms as well as carbon and nitrogen atoms, constituting the collagen-based scaffold of the corneal stroma, are broken down, and volatile tissue fragments are formed. This process is referred to as photoablation. The range of photoablation, i.e. the thickness of the corneal stroma layer removed by the laser, is closely related to the size of the defect to be corrected.

LVCs are divided into surface ablation and deeper stromal procedures. Surface procedures involve removal of the corneal epithelium followed by laser ablation of the exposed Bowman's membrane and underlying stroma. The most common surface ablation techniques include photorefractive keratectomy (PRK), laser subepithelial keratomileusis (LASEK), and epi-Bowman keratectomy (EBK). As for stromal procedures, two types have been distinguished. The first type is the so-called flap procedure, which consists in the preparation of a layered corneal flap with a thickness of 100–140 microns using a femtosecond laser (femtosecond laser-assisted in situ keratomileusis, femtoLASIK) or a microkeratome (laser in situ keratomileusis, LASIK), followed by ablation of the exposed corneal stroma with an excimer laser. The second type of stromal procedures is a technique in which a femtosecond laser dissects a microlens in the corneal stroma, which is then extracted outside through a 2–3-mm arcuate incision (small incision lenticule extraction, SMILE)[4].

LVC is followed by corneal healing, which is an important factor influencing its effectiveness and safety. The range of interventions and subsequent healing processes are significantly greater after superficial procedures than after stromal surgeries, as they involve the removal of the epithelium, Bowman's membrane and part of the anterior corneal stroma, while stromal procedures mainly involve the corneal stroma. Myofibroblasts, characterised by reduced transparency and playing a major role in the remodelling of the extracellular matrix by stimulating the production of collagen, glycosaminoglycans, the activity of collagenases and metalloproteinases, are the most important element of the corneal healing cascade following laser ablation. Corneas with large counts of myofibroblasts are more likely to develop haze and partial recurrence of the refractive error (so-called regression)[5]. Corneal haze is a consequence of an imbalance between the factors promoting the formation of myofibroblasts (mainly the transforming growth factor beta, TGF-β) and factors causing their apoptosis (mainly interleukin 1, IL-1) in favour of the former. General factors that promote myofibroblast proliferation include exposure to UV

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radiation, genetic factors and certain autoimmune diseases. It was shown that apoptosis and keratocyte proliferation, as well as myofibroblast production are significantly less pronounced in LASiK-treated eyes than after PRK for myopia[6]. Refractive corneal surgeries are also associated with damage to the sensory afferent fibres of the subepithelial plexus of the ocular branch of the trigeminal nerve, the clinical consequences of which include impaired reflex tear secretion by the lacrimal gland and dry eye syndrome (DES). The incidence of DES is higher after flap procedures (femtoLASIK, LASIK) than after superficial procedures or the SMILE method, and is estimated at 20–40%; the symptoms are mild and resolve within a few weeks in the vast majority of patients[7].

Abnormal corneal healing process may be associated with such complications as refractive error (overcorrection, undercorrection, secondary astigmatism), severe DES, ulceration, haze, corneal melting or ectasia. According to the guidelines of the American Academy of Ophthalmology (AAO) and the Food and Drug Administration (FDA)[8], the coexistence of autoimmune connective tissue diseases, such as rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), psoriatic arthritis (PsA), sarcoidosis, ankylosing spondylitis (AS), multiple sclerosis (MS) and scleroderma, is a contraindication to LVC procedures. These guidelines were proposed several years ago and were based on case reports or recommendations developed for other ophthalmic procedures. Concerns over an increased risk of an inflammatory ocular reaction, unpredictable corneal healing process and remodelling, including ulceration, haze, scarring and corneal melting were the main reason for considering these conditions as exclusion criteria. Patients with systemic vascular diseases are more likely to develop keratoconjunctivitis sicca (KCS), scleritis, episcleritis, and uveitis, which may complicate the outcome of any surgical ocular intervention. Furthermore, immunosuppressants commonly used in these conditions may increase the risk of infection. In their study in a group of 622 patients (1,224 eyes) with autoimmune diseases, Schallhorn et al.[9] reported 3 cases of postoperative anterior uveitis (2 patients with RA and 1 patient with AS with the presence of human leukocyte antigen B27 – HLA-B27). Two of these patients had a history of uveitis.

Several studies have been published in the past decades that showed an uncomplicated visual recovery in the majority of LVC-treated patients with well-controlled autoimmune disorders[9–11]. This paper presents the current literature and discusses up-to-date recommendations on the general contraindications to LVCs.

AUTOIMMUNE DISORDERS

According to the current AAO guidelines (2023)[8], only active (uncontrolled) autoimmune disorders are an absolute contraindication to LVC, while inactive well-controlled diseases are considered a relative contraindication. Decisions about qualification for surgery should be made individually.

The so far largest retrospective analysis published by Schallhorn et al.[9] in 2016 included 1,224 eyes in 622 patients with well-controlled autoimmune disorders, who were treated with LASIK or PRK (with intraoperative 0.02% mitomycin) in the years 2008–2015. A total of 825 myopic, 377 hyperopic and 22 mixed astigmatism eyes were included in the study. Concomitant autoimmune disorders included RA (n = 315 patients), SLE (n = 121), PsA (n = 65), sarcoidosis (n = 62), AS (n = 40), MS (n = 12) and scleroderma (n = 7). LASIK and PRK were performed in 1,114 and 110 eyes, respectively. [The mean postoperative spherical equivalent refractive error was less than ± 0.5 diopters (D) in 81.8% of LASIK-treated eyes and 82.3% of PRK-treated eyes]. Postoperative complications included anterior uveitis (in 3 patients) and corneal melting (in 1 patient), which successfully resolved with topical therapy. Based on their observations, the authors of the study concluded that LVCs may be considered in patients with well-controlled, inactive autoimmune disorders, and without ocular symptoms. LASIK procedures should be preferred in these patients due to the shorter healing time and lower risk of haze and scarring than after PRK procedures. However, the conclusions from Schallhorn et al.[9] should be interpreted with caution due to the limitations of the analysis. Firstly, a certificate obtained from a family doctor or rheumatologist was the only confirmation of remission of the underlying disease lasting for at least 6 months; secondly, the paper offers no information on the perioperative use of systemic agents such as glucocorticoids or immunosuppressants by patients. According to published data, DES of varying severity is the most common transient complication after laser refractive surgery[12,13]. Primary (preoperative) eye dryness is the most important risk factor for postoperative DES.

Preoperative identification of patients at particular risk of this complication, e.g. using the Schirmer test, is very important. DES symptoms usually resolve within a few weeks. In most cases, frequent use of preservative-free artificial tears is sufficient to relieve DES symptoms. However, tear plugs may be needed in some cases. It is believed that the risk of DSO after LASIK is lower with femtolaser flap than with microkeratome flap[14]. Primary Sjögren's syndrome and uncontrolled, active autoimmune disorders are considered an absolute contraindication to laser refractive procedures due to the high risk of intensified severe DES and abnormal healing process[11].

Inflammatory bowel diseases (IBDs) are a group of chronic inflammatory GI disorders that may adversely affect the healing processes in patients undergoing LVCs. Carp et al.[15] presented a case of a 50-year-old female patient with bilateral stromal keratitis and corneal melting

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along the margin of the corneal flap 3 days after an uncomplicated LASIK procedure. However, the patient concealed her history of a total colectomy she had undergone 10 years earlier for ulcerative colitis from the surgeon. Symptoms resolved with aggressive topical and systemic steroid therapy. No symptom recurrence was observed in a 12-month follow-up. In turn, Aman-Ullah et al.[16] described 2 clinical cases of patients with Crohn's disease in remission, who developed bilateral keratitis with inflammatory infiltrates a few days after LVC. A 40-year-old woman underwent LASIK, and a 30-year-old man underwent PRK. The patients had been in remission for at least several years and were not on any medications during the procedure. Symptoms resolved with topical and systemic steroid therapy. During the 7-month follow-up period, a single relapse was reported in the LASIK patient, also with good response to steroid treatment. Moshirfar et al.[17] reported the results of a study in a slightly larger group of IBD patients. A group of 11 patients (21 eyes), i.e. 6 patients with ulcerative colitis and 5 patients with Crohn's disease, underwent LASIK (9 patients, 17 eyes), PRK (1 patient, 2 eyes) and SMILE (1 patient, 2 eyes). All patients achieved the best uncorrected distance visual acuity of 20/20 at 3 months postoperatively. The mean follow-up period was less than 9 months. Symptoms reported during the follow-up period were typical of this procedure and included dry eyes, irritation, foreign body sensation, and blurred vision. Throughout the follow-up period, symptoms gradually improved, and none of the patients experienced postoperative exacerbation of their underlying disease. Despite therapeutic success, the authors point out the increased risk associated with laser refractive procedures in IBD patients. Currently, however, there are no guidelines to follow in order to properly qualify such patients.

DIABETES MELLITUS

Diabetes mellitus (DM) is a lifestyle disease that affects an increasing number of people worldwide. According to data from 2017[18], the National Health Fund (NFZ) financed the treatment of DM in approximately 2.5 million Poles (8% of adult citizens), with type 2 diabetes accounting for the majority of cases. It is estimated that the number of diabetic patients in Poland will exceed 4.2 million in 2030[18].

According to the AAO[8] guidelines, DM is a relative contraindication to LVC due to refractive instability and the risk of impaired healing processes associated with inadequate metabolic control. In 2012, Simpson et al.[19] published a review paper on the safety of LASIK procedures in diabetic patients. Three 2002–2006 scientific studies in a total of 119 DM patients, including 2 patients with features of mild nonproliferative diabetic retinopathy were analysed. According to the authors of this study, patients with well-controlled glucose levels for at least 12 months, no systemic complications or ocular symptoms, i.e. DES, corneal sensory disturbances and diabetic retinopathy, may be considered for LVC. In the case of a positive qualification, LASIK should be the preferred correction method due to the less intense healing processes.

PREGNANCY AND BREASTFEEDING

Hormonal changes that affect corneal structure and properties occur in pregnant and breastfeeding women. It has been shown that during pregnancy there are changes in the mechanism of ion transport in the tear ducts[20], and that oestrogens increase the production of pro-inflammatory cytokines in corneal epithelial cells, which results in reduced tear secretion[21]. According to Moshirfar et al.[22], LASIK or other types of refractive surgery are not recommended until breastfeeding has ceased, regular menstruation has returned, and refraction has stabilised. Patients planning pregnancy after LASIK should also be informed of possible defect regression if pregnancy occurs within 12 months of surgery. This scenario is possible due to corneal remodelling caused by pregnancy hormones. Jani et al.[23], based on the analysis of a large amount of clinical data (17 papers), found that hormonal fluctuations during pregnancy and in the perinatal period may increase the risk of corneal ectasia or its progression in eyes treated with LASIK shortly before pregnancy. Therefore, careful monitoring of at-risk women is recommended for early cross-linking (CXL) surgery and to avoid deterioration of visual acuity. Cases of exacerbation of eye dryness in pregnant patients after LASIK, who required intensive moistening of the eye surface and the use of punctal plugs to inhibit the outflow of tears from the conjunctival sac, have also been reported[22].

PHARMACOTHERAPY

The 2023 AAO guidelines[8] list therapies that are a relative contraindication to LVC. These include, among others, isotretinoin, amiodarone and sumatriptan as well as implants with levonorgestrel.

Isotretinoin is a synthetic derivative of vitamin A used to treat severe acne. It is secreted with tears and promotes DES in up to 50% of patients during the first 5 weeks of treatment[24]. It is suggested in literature that vision correction surgery should be considered not earlier than six months after isotretinoin discontinuation[25]. In their 2018 retrospective study, Ortega-Usobiaga et al.[26] compared postoperative outcomes in 113 patients (219 eyes) undergoing LASIK or PRK, who were perioperatively on isotretinoin, with the control group. No significant intra- or postoperative complications were identified in the study. There were no significant differences between the groups in terms of visual acuity, postoperative spherical equivalent, success index, predictability of procedure

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or safety index. No clinically significant eye dryness was observed in the analysed groups. The authors concluded that LASIK and PRK can be performed in patients on isotretinoin.

Amiodarone is a class III drug according to the Vaughan Williams classification that blocks potassium channels in the myocardium with subsequent slowing of the conduction of electrical impulses in all myocardial cells. Formation of deposits in the basement membrane of the corneal epithelium and the development of vortex keratopathy, which is found in up to 90% of patients at 6 months after treatment onset, are undesirable effects of chronic therapy with this drug[27]. A retrospective study by Ortega-Usobiaga et al.[28] found no significant intraoperative or postoperative complications in a group of 20 LASIK or PRK-treated patients (33 eyes) on chronic amiodarone. The authors concluded that LASIK and PRK procedures were not associated with a significant risk of complications in patients receiving amiodarone.

Sumatriptan is a serotonin 5-HT_1 receptor antagonist used to treat migraine headaches. It is suspected that this drug has a negative effect on the ocular surface and the tear film, which may increase the incidence of intra- and postoperative corneal epithelial defects[29]. Hardten et al.[29] assessed a group of 28 patients (54 eyes) on sumatriptan and 28 controls (54 eyes) not using this drug. The rates of corneal epithelial defects after LASIK surgery were assessed. No significant differences were found in the incidence of this complication between the compared groups (11.1% vs. 9.3%, $p > 0.05$). The authors of the study concluded that the use of sumatriptan for migraine headaches does not significantly increase the rates of epithelial defects after LASIK.

The authors of these studies call for reconsidering the rationale for not qualifying patients using selected systemic treatments for LVC. However, due to their potential impact on the course of healing and scarce scientific evidence for their peri- and postoperative safety, it seems reasonable to discontinue these treatments at least several months before a planned surgery.

Hormonal contraception and hormone replacement therapy are not contraindications to laser refractive procedures. Hormonal treatment should not be altered or initiated at least 3 months pre- and postoperatively.

OTHER DISORDERS

In the case of thyroid diseases (Hashimoto's disease), LVC may be considered in patients with regulated hormonal balance. Studies have shown no significant corneal scarring in individuals prone to keloids who underwent PRK and LASIK[10]. In turn, other authors suggest that stomal methods (LASIK, femtoLASIK) should be preferred in these patients due to potential healing problems. Although the age below 18 years is an absolute contraindication to laser refractive surgery, PRKs are performed in children in specialised centres to treat anisometropia and amblyopia[4].

HIV (human immunodeficiency virus) seropositivity is a relative contraindication to LVCs. In the Refractive surgery in the HIV-positive U.S. Military Natural History Study Cohort[30], in 2,073 HIV-positive patients, 79 patients underwent LASIK, PRK, or radial keratotomy (RK). Complications in the form of corneal ulceration (5 patients) and non-specific keratitis (1 patient) were described in a total of 6 cases (7.6%), including five PRK patients and one RK case. The study confirmed the higher safety of LASIK than PRK in this patient subpopulation.

Mental disorders with maintained emotional stability are another relative contraindication to LVC. Mental problems affect an increasing number of people, especially young, professionally active and prone to stress. A large proportion of these patients use anxiolytics or antidepressants. In such cases, it is worth seeking additional opinion from a family doctor or psychiatrist, as depression has been shown to negatively affect the patient's well-being and satisfaction with the quality of vision after LASIK[31].

Absolute and relative contraindications to laser refractive surgery are presented in Tab. 1.

CONCLUSIONS

Knowledge of contraindications to laser refractive procedures is a prerequisite for the proper qualification process and safety of planned LVC procedures. Current guidelines of ophthalmological societies and agencies issuing opinions on medical procedures should be considered when making therapeutic decisions in patients with systemic comorbidities or risk factors. In the last two decades, many papers have been published confirming the safety of LVCs in selected general diseases. However, these are retrospective studies or case series and their results should be interpreted with caution. Active or uncontrolled autoimmune disorders and other autoimmune diseases, pregnancy and breastfeeding are absolute contraindications to LVCs. The decision to perform LVC in a patient with general comorbidities or risk factors constituting a relative contraindication should be made individually by an experienced refractive surgeon, bearing in mind that quantitative estimation of surgical risk is not possible. It is also recommended that decisions should rely on the current written opinion of a specialist doctor, confirming that the underlying disease is inactive and properly controlled. Patients from the risk group should be informed about the increased risk of postoperative complications, including DES, which may persist chronically, and this information should be included in the informed consent form for the procedure. In some cases, surgery limited to one eye may be considered, with a planned temporary postponement of treatment of the

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Absolute	Relative
• Active or uncontrolled autoimmune or other immune-mediated disorders • Pregnancy and breastfeeding • Age <18 years • Sjögren's syndrome • Psoriatic arthritis • Inherited connective tissue diseases • Uncontrolled diabetes or diabetic organ complications • General steroid therapy • Chemotherapy • Active mental illness or emotional instability • Unrealistic expectations of the patient	• Autoimmune or other immune-mediated disorders in remission • Diabetes mellitus • Age 18–21 years • Hashimoto's disease • HIV (seropositivity) • Certain medications (e.g. isotretinoin, amiodarone, sumatriptan, levonorgestrel implants, colchicine) • Immunosuppressants • Biologics • Keloids • Mastocytosis • Well-controlled mental illnesses
HIV – human immunodeficiency virus.	

Tab. 1. General contraindications to laser vision correction based on current literature[8,10,17]

other eye. In the case of doubts or incomplete information on general diseases and risk factors, the situation should be clarified or a decision should be taken not to proceed with the surgery.

Conflict of interest

The authors do not report any financial or personal connections with other persons or organisations, which might negatively affect the contents of this publication and/or claim authorship rights to this publication.

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