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ETHICAL CONSIDERATIONS IN LASER-ASSISTED REFRACTIVE SURGERY

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Abstract: *Introduction.* Clinical ethics based on principlism of Tom Beauchamp and James Childress have become an inherent part of medical practice. Laser-assisted refractive surgery corrects refractive errors by remodeling the anterior corneal curvature, and is perceived by the patient as a simple, low-risk intervention that provides excellent measured visual results and quality of life improvement.

Materials and methods. A wide-targeted search of Clarivate Web ok Knowledge and PUBMED databases was performed for papers within the last 15 years concerning patient selection for refractive surgery, efficacy and safety of the procedure, complications and legal recourse.

Results and discussion. Laser-assisted refractive surgery was found to have high perceived and effective beneficence for the patient, providing spectacle-independent vision with excellent safety profile. Non-maleficence requires completeness of preoperative screening for conditions such as corneal ectasia or managing systemic disease such as autoimmune disorders. It is critical for autonomy to fully inform the patient on a wide range of possible complications or unwanted results including quality of vision effects such as photic phenomena (glare and rainbow glare, haze, halos) or variance in the healing process that can lead to refractive regression, buildup of corneal haze or other healing complications. Justice was sought for negligence in treament or informed consent.

Conclusion. Refractive surgery satisfies the bioethical principles, being benefic both to the patient and to society. Completeness of information for the patient is of utmost importance. Minimizing risk and providing therapeutic management to complications while preserving the patient-physician relation is a mark of professionalism and averts harm and dissatisfaction to the patient.

Keywords: laser-assisted refractive surgery, cornea.

INTRODUCTION

Bioethics or Biomedical ethics is an inherent and inseparable part of clinical medicine [1,2] with the physician having an ethical commitment towards benefiting the patient, avoidance or curtail of harm, and respect towards patient autonomy with regards to values and preferences [1]. Clinical ethics has been fundamentally built upon Principlism [3], the bioethical theory championed by Tom Beauchamp and James Childress [4] and centered on the four moral principles of beneficence, non-maleficence, respect for autonomy, and justice [3]. In accordance with biomedical ethics, physicians performing surgical interventions considered elective, such as refractive surgery, find themselves at the crossroads between the patient's best interest, quality-of-life, and "benefits and burdens" judgements [3]. Laser-assisted refractive surgery corrects refractive errors (myopia, hyperopia, astigmatism, and presbyopia [5]) using laser-assisted surgical techniques that reshape the anterior corneal curvature by removing tissue from the corneal stroma. The cornea provides two-thirds of the eye's refractive power [5] and is composed from anterior to posterior of the following layers: epithelium with surface cells and a basement membrane, Bowman's membrane, the stroma which comprises collagen fibers aranged into fibrils and represents the densest layer at 80-85% of corneal thickness, Descemet's membrane and the endothelium [6]. By reshaping the structure of the corneal stroma via precise laser-assited removal of tissue a dioptric correction for emmetropic vision is achieved. Surface ablation techniques first completely remove the

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epithelium, followed by laser-ablation of Bowman's layer and the stroma. Classic Photorefractive keratectomy PRK uses manual epithelial debridement, while the newer transepithelial photorefractive keratectomy Trans-PRK performs both epithelial debridement and stromal remodeling using the same ultraviolet (UV) excimer laser in a two-stepped process, first the epithelium, then the stroma. Laser-assisted in-situ keratomileusis LASIK first creates a corneal hinged-flap using an infrared femtosecond laser which is then lifted away from the path of the laser, followed by stromal ablation using a UV excimer laser and reseating the flap on top of the ablation zone [5]. Several variants of this technique have been developed: epitelial laser-assited in-site keratomileusis epiLASIK, laser epithelial keratomileusis LASEK. Small-lenticle extraction SMILE is a wholly femtosecond laser technique which cuts in three-dimensions a lenticle in the corneal stroma which is then extracted trough a small incision [5]. In more niche cases, the excimer laser can also be used to create various incisions with extreme precision allowing for the surgical techniques such as for implantation of intrastromal corneal ring segments (ICRS) [7-8] or corneal stromal inlays (CSI) [7-8] or performing astigmatism correction incisions [7]. For patients outside the indications of laser-assited refractive surgery, a solution is the replacement of the natural lens with an artificial intraocular lens (IOL) correcting spherical diopters or also correcting cylinder diopters (toric IOL) [9-10] for achieving a refractive goal in the absence of lens-based pathology (clear lens exchange) or in the presence of lens opacification (cataract) [9]. IOLs cannot modify their shape in a similar fashion to the accomodation reflex of the natural lens for providing both far, intermediate and near vision, and as such specialised multifocal [9] or extended depth-of-field IOLS [11] are required, with their toric versions required for cyllinder diopter correction [9]. Other intraocular refractive surgery techniques include implantation suplimentary intraocular lens such as piggy-back IOL that supplements the refractive power of the natural lens while preserving the accomodation reflex. Intraocular refractive surgery carries additional risk owing to operating intraocularly, with laser-assited surgery showing better outcomes in efficacy and predictability [12] and being the preferred method for managing and correcting residual refractive error [12-13]. Other historical techniques have been employed such as radial keratectomy and corneal incisions using specialised surgical blades, however these techniques have been superceeded by the improved accuracy and safety profile offered by laser-assisted procedures, with the excimer laser capable of performing various incisions with extreme precision allowing for the surgical techniques such as the implantation of corneal stromal inlays or astigmatism correction incisions.

MATERIALS AND METHODS

A wide-targeted search of the Clarivate Web of Knowledge (ISI Thompson) and PUBMED Database was performed in Octomber 2022 for papers from the past 15 years using several search terms such as "refractive surgery" "refractive surgery complication" "refractive surgery ethics" "refractive surgery legal" "refractive surgery malpraxis", and included additional specific terms such as "PRK complication" "LASIK complication" or searching directly for the complications such as "corneal haze". We performed a detailed analysis of the steps of the surgical process of conducting refractive surgery interventions using established laser-assisted stromal removal techniques such as PRK, LASIK and epiLASIK, LASEK, Trans-PRK, SMILE. Bioethical implications were analyzed in performing patient selection versus known contraindication and borderline scenarios, patient aytonomy and completeness of the informed consent, perceived and effective beneficence of the surgery, information, and prevention of postoperative complications in accordance with non-maleficence and if present, management and prognosis of said complicaitons. From both the ISI Thompson and PUBMED database papers were further filtered into the following groups: papers detailing results and safety of refractive surgery; detailing complications; detailing malpraxis legislation and cases. A literature analysis of refractive surgery was performed in accordance with the fundamental principles of bioethics and perceived slight to these principles.

RESULTS

Perceived beneficence for the patient

Refractive surgery addresses a growing need for the correction of refractive errors which are a leading cause of visual impairment across the world [6,14-15]. Myopia presents a global burden, affecting nearly 30% of the world population and expected to rise in prevalence to over 50% in 2050 [6,14], potentially affecting billions of people [6]. Furthermore, considering the lifetime-cost incurred by optical correction to a patient using spectacles or contact lenses, refractive surgery was found by Mohammadi *et al.* less costly by a significant margin [15].

The patient's desired quality-of-life in accordance with the expected results of the refractive surgery procedure, combined with the perceived simplicity and low risk of laser-assited refractive surgery, is the main driving force in patient addressability towards the refractive surgeon. A smaller patient cohort addresses the refractive surgeon for the purpose of enlisting into a military profession or a certain occupation which requires 20/20 or better vision and where correction by other optical means is either not allowed or deemed impractical [16-17]. As such, laser-assited refractive surgery is either an elective/optional vision enhancement surgery considered at the patient's behest in a private practice enviroment or provided by a larger organization such as the military [18]. The high media visibility of private practices, acceptance of the procedure within the military branches and therapeutic effect of greatly increasing quality of life together with an excellent safety profile reported by literature hype up refractive surgery and increase expectations from the patient, which is also usually younger and risk adverse.

Effective Beneficence and surgical safety

Laser-assisted refractive surgery is an effective surgical intervention for achieving better uncorrected distance visual acuity (UCVA). A search of the National Library of Medicine's PubMed highlighted papers with large patient databases reporting on the effectiveness of common refractive surgical techniques: Kamiya K. *et al.* multicenter retrospective study of 78248 eyes [19] reported an overall 20/20 or better (considered clincally perfect) visual acuity in 69.987 (99.5%) and 67.512 (95.9%) eyes subgroups via LASIK surgical correction [19]. Sandoval HP *et al.* review of 97 papers published between 2008 and 2015 [20] reported better than 20/40 (considered spectacle-independent, however 50% lesser than clinically perfect 20/20) uncorrected visual acuity in 99.5% (59 503/59 825) [20], with the spherical equivalent refraction within 1 diopter distance of the target refraction in 98.6% (59 476/60 329) of eyes [20], with only 1.2% (129/9726) of patients dissatisfied with LASIK results [20]. Gomel N. *et al.* did not find a statistical difference when comparing effectiveness of LASIK *vs.* PRK [21], nor did Zhang Y. when comparing efficacy and safety of FS-LASIK *vs.* SMILE technique in 1101 eyes [22]. Taneri *et al.* concluded that long-term studies with follow-up periods of at least 10 years have shown that PRK and LASIK carried earlier in the days of medical excimer lasers have a very high level of safety [23], and reported no clear superiority for any procedure (LASIK, PRK, SMILE) [23]. Wen. D. *et al.* examined randomized controlled trials for FS-LASIK (femrosecond-based laser in situ keratomileusis) finding no statistical difference in visual outcomes *vs.* other laser-assisted surgical techniques [24], and Vestergaard reported no difference in safety and efficacy for ReLEx femtosecond small-lenticle extraction, similar to SMILE, *vs.* femtosecond LASIK (FS-LASIK). In conclusion, no matter the surgical technique chosen, laser-assited refractive surgery achieved excellent results, providing clear patient beneficence and without differentiating patients based on the technique chosen or the medical devices employed. For military applicants Godiwalla RY *et al.* compared outcomes of LASIK and PRK, reporting stable refractive results within 0.1 D increase in myopia per year and strong keratometric stability [26].

Non-maleficence – Patient selection, management of complex, borderline cases

Safety profiles of each surgical technique were found to be similarly excellent when comparing extensive reviews adressing the last 10-15 years of publications on refractive surgery [16-26], concluding that the principle of non-maleficence is clearly addressed. However, adequate patient selection is important for achieving optimal results, and as such will be presented at large.

Keratoconus and corneal ectasia screening is required preoperatively for laser-assisted refractive surgery. A rotating Scheimpflug tomograph creates a 3D-scan of the entire cornea and measures the anterior and posterior corneal surface. Placido-disk based cornea topography compliments by quantifying the anterior corneal surface [27, 28], representing anterior surface curvature data via a map of the corneal surface, which is essential for enhanced calculation of the ablative correction required and is heavily used in newer, topography-guided refractive surgery techniques. These devices are also optimal in screening for corneal ectrasia and keratoconus, which is a bilateral and asymmetric disease resulting in progressive thinning and steeping of the cornea [29]. Performing refractive surgery via stromal and/or epithelial ablation on a mechanically unstable cornea is contraindicated. A large part of the diagnosis and management of keratoconus centers around prevention and early treatment of the disease to halt progress [29] via therapeutic intervention such as performing corneal cross-linking (CXL) [30] which used Ultraviolet A light-based photoactivation of riboflavine to induce corneal crosslinking, mechanical stiffening, and can also reduce minor refractive errors trough topographically guided photorefractive intrastromal CXL (PiXL) [30] or novel techniques such as Nonlinear optical crosslinking (NLO CXL) [31]. Screening for keratoconus and evaluating for refractive surgery were found to be basically intertwined, with the investigative apparatus being the same, and the lasers used in refractive surgery capable of precisely photoactivating riboflavine, such as in PiXL crosslinking technique using femtosecond laser, or combining crosslinking and excimer UV laser-treatment in novel protocols [32]. Novel artifical intelligence applications have been used successfully to screen for keratoconus, using the powerful topography platforms of refractive surgery systems [33].

Autoimune disorders such as rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), seronegative spondyloarthropathies (SpA), Sjogren's syndrome can exhibit ophthalmic manifestations such as keratoconjunctivitis sicca, uveitis, or peripheral ulcerative keratitis and corneal melting and perforation [35]. Several studies were reported on patients which had achieved control of their autoimmune conditions for at least 6 months before the surgery, showing no adverse effect [34] and no adverse effect such as corneal haze, tear film abnormality, melting, ulceration, diffuse lamellar keratitis (DLK) and infection [35]. Cobo-Soranio *et al.* [35] performed LASIK in patients with autoimmune connective-tissue disorders (62), psoriasis (91), itnestinal inflammatory diseases (67), diabetes mellitus (44) and history of abnormal keloid formation (18), with 29 patients (56 eyes) under immunosuppressive therapy at the moment of surgery and found only worse refractive outcome and predictability in the presence of collagen vascular disease [35]. Schalhorn et. al studied 622 patients (1226 eyes) [36] with underlying collagen vascular or autoimmune disease, finding good refractive outcomes within 0.5 D of targeted emmetropia via LASIK (81.8%) [36] and PRK (82.3%) [36] and similar safety and efficacy in these patients. However, in the case of underlying, undiagnosed, and untreated autoimmune conditions Li and Li reported unilateral corneal melting in 12 patients [37], which tended to begin from the rim of the LASIK corneal flaps and brought attention that LASIK surgery could be an inductor of corneal melting [37], with patients later diagnosed with systemic lupus erithematous, Sjogren syndrome and rheumatoid arthritis. Refractive surgery could also exacerbate Sjogren syndrome (SS) tear film instability and lead to recalcitrant dry eye symptoms [34], such as reported by Liang *et al.* [37] in patients with SS and preoperatively mild or no eye symptoms which developed severe dry eye and punctate epithelial keratopathy, followed by refractive regression [38]. Moshirfar M. *et al.* concluded that patients with Heritable Disorders of Connective Tissue (HDCTs) should not be immediately disqualified [39], with minor ocular manifestations apt for LASIK and patients with signs of corneal thinning, as discussed previously with keratoconus [28-31], eligible for combining cross-linking with refractive surgery [32] or for surgical alternatives such as phakic intraocular lens implants [39]. Weighing up the individual risks is required in tandem with informing the patient [40], with a decision taken on a case-by-case basis.

Non-maleficence, justice: Postoperative complications of refractive surgery

Tear film abnormality and dry eye is the most common postoperative complication of corneal refractive surgery [41], and has pathophysiology in corneal sensory nerve dysfunction, ocular surface desiccation, glandular apoptosis, and ocular surface inflammation [41]. Several refractive surgery techniques, such as PRK and Trans-PRK surgically destroy the epithelium and the corneal epithelial basement membrane responsible for homeostasis and wound healing to perform stromal ablation. Sharma B. *et al.* remarked that LASIK, an epithelium-preserving technique, also presents a strong association with dry eye disease. In patients with Sjogren's Syndrome, LASIK surgery can be an inductor and exacerbator of dry eye symptoms [38] which can lead to severe dry eye and punctate epithelial keratopathy, followed by refractive regression [38]. Testing of the tear film stability and tear secretion should be performed before surgery, and in certain cases therapeutic steps taken to improve the tear film before surgery.

Regression of measured refraction after refractive surgery [42]. Despite accurate preoperative calculations of the ablative profile, the long-term cellular response of the cornea remains a patient-specific and largely unknown parameter, which can lead to regression from the ideal postoperative refraction [42] and may even require follow-up enhancement surgeries, exposing the patient to additional risk [42] and the surgeon to real litigation risk. The epithelium overlying the flattened regions where stromal corneal ablation was performed can undergo gradual hyperplasia, thickening and modifying measured refraction. Some degree of thickening occurs regradless and is increased by higher correction values [43-44] (so larger ablation of the corneal stroma): 7 microns (μm) at 3-6 months postoperative for low myopia correction (-1 to -4 D), 9 μm for intermediate myopia (-4.25 to -6) and 12 μm for high myopic correction (-6.25 to -13.5) for LASIK patients [43]. Concerning the corneal stroma initial postoperative fluid swelling and inflammation occurs, resulting in a transient myopic shift [42]. Afterwards, activated stromal keratocytes proliferate and exude glycosaminoglycans, fibrin, and other extracellular matrix components [42], remodeling the corneal architecture. According to Ivarsen A. *et al.* [44], stromal thickness increased 25.3 ± 17.2 μm during the year postoperative, correlating with refractive regression, being most pronunced after PRK surgery, while after LASIK the regrowth was restricted to the residual stromal bed. Postoperative refractive changes correlated with changes in stromal thickness [44] for both PRK and LASIK.

Abnormal healing such as corneal haze and epithelial ingrowth. Arising early in the postoperative period in 0-3.9% of primary treatment cases [45], post-LASIK epithelial ingrowth can range from asymptomatic to severe visual impairment and flap melting keratoplasty [45]. Corneal haze is caused by alternations in the healing process and occurs in a small percentage of eye (0.3% to 3%) [46]. The epithelial basement membrane has an important role in wound healing and prevention of haze [46]. PRK and Trans-PRK technique ablates trough the epithelium, permanently destroying the basement membrane [46]. Most commonly haze appears transitory between 1 and 3 months postoperative and usually resolves within 1 year [46], however late onset haze can appear at 2 and 5 months postoperative [46] and can last for years, severely compromising vision [46]. Therapeutic interventions include mechanical debridement, mitomycin C, or reintervention using phototherapeutic keratectomy (PTK) or lamellar keratoplasty [46].

Photic phenomena: glare, haze, halos can appear after performing corneal refractive surgery and are important considerations for the patient's quality of vision which can be hampered even in the absence of a measured decrease in visual acuity. These phenomena are especially manifest in high-contrasting enviroments where there are intense light sources over a dim background, such as a night-driving scenario. Several sources of photic phenomena after laser-assited refractive surgery have been identified.

Angle kappa is the measured angular distance between the visual and pupillary axes [47] and is currently measured by either cutting-edge topography platforms for refractive surgery or more classically via synoptophore or major amblyoscope [47]. More simply, the patient's visual axis does not exactly concide with the observed pupillary center measured via the perpendicular line passing trough the center of the pupil perpendicular to the cornea (EPC) [47] or the highest elevated central corneal point (the corneal vertex), and physiological variance is inherent, with more in hyperopic eyes. Basmak *et al.* reported angles kappa of 5.65 ± 0.10° and 5.73 ± 0.10 in hyperopic eyes [48] *versus* emmetropes 5.55 ± 0.13° and 5.62 ± 0.10° [48] *versus* myopes 4.51 ± 0.11° and 4.73 ± 0.11° [48]. According to Park CY. *et al.*, most refractive platforms center the keratorefractive procedure over the EPC (pupillary center) [47]. To achieve optimal visual quality for the patient a lateral alignment accuracy of 0.07mm or better for large 7.0mm pupils and 0.2mm or better for a smaller 3mm pupil is required [47], and in cases of higher angle kappa performing the ablation using only the EPC measurement could lead to decentration and visual complaints of glare, distortion, diplopia or reduced visual acuity [47]. Accurate measurement of the angle kappa and programing this parameter into the ablation calculation requires high-performance corneal topography and employing a topography-guided ablation technique [48] or more recent analytical-engine calculation formulas. Wave-front guided treatment [48], while excellent, produces ablation-area calculations based on raytracing centered on the EPC [47] and can misrepresent the patient's true vision in borderline, large angle-kappa cases [47].

Other sources of photic phenomena include the early preoperative period before 6 months [49] due to ongoing healing and integration of the post-ablative area into surrounding corneal tissue. "Rainblow glare" is thought to occur through light transmissive diffration grating on this posterior surface of the corneal flap created by femtosecond laser [50] and is described by the patient as 4-12 spectral bands of light radiating symmetrically from a point source of light. [50]. In rare cases patients reported seeing continual halos of color rather than discrete bands [50]. The femtosecond laser reshapes the cornea by producing photodisruption at the molecular level to generate plasma, producing spherical microcavitation bubbles that remove the corneal tissue [51-52]. As such the surface of the laser-ablated zone presents a molecular surface akin to a castle wall battlement, with lower spherical ares of removed tissue (craters [52]) intertwined with raised triangular spaces in-between the spherical areas where microcavitation was produced by the femtosecond-laser. Confocal microscopy has demonstrated the presence of grid-like pattern of hyperreflective spots, corresponding to the raster pattern of the femtosecond laser [52]. Lifting the flap and perfoming a small corrective ablation on the posterior flap sourface could be warranted if symptoms are persistent [52]. Photic aberrations can also be induced in the transitional area (between the central, optical area, usually 6mm in size) and the end of the ablative zone (usually 8 or 9mm in total diameter). In the presence of large pupil size, larger than the optical ablative zone such as in a very low-light enviroment, light rays from light sources can hit the transition zone and diffract differently *vs.* light rays arriving in the optical zone, producing photic phenomena. As technological progress is being made in more accurate and advanced topographical measurement and better lasers allowing large enough ablative zones, photic phenomena are expected to be minimized. New aberrometry devices can quantify visual abberations with excelent measurement accuracy and repeatability [53], safety and efficacy [53], and will probably complete the topographic corneal picture, offering better ablative calculation and less postoperative photic phenomena.

Sight-threatening complications can severely compromise postoperatory results, affecting patients and placing a high burden on the physician.

Flap-induced complications are caractheristic for LASIK, with the severe ones being flap dislocation or detachment which can occur early before reepithelization, within the first 24 hours after the surgery [54]. Integration of the flap with the corneal stromal bed remains an anatomically weakspot, and deatachment can also occur after ocular trauma. Malposition of the flap requiring reintervention has been reported for 0.1-2.5% of cases [54], with flap striae (tenting of the flap) being more common *vs.* dislocation.

Inflammatory activity can present as diffuse lamellar keratitis (DLK) [54], with severe stage 4 DLK posing danger of permanent scarring and dioptric shift. Marginal keratitis involves the peripheral flap, the corneal between the flap and limbus or both and is manifest via sterile corneal infiltrates [54].

Infectious keratitis is a corneal infectious process which can appear in up to 1.5% of LASIK surgeries, and post-LASIK is mostly caused by atypical mycobacteria (48-53%), gram-positive bacteria (29-39%) or fungi (10%) [54]. Early diagnosis and treatment is essential for prevention of lasting visual impacts, such as scarring from corneal ulcerations. Refractive surgery may reactivate latent Herpes simplex and zoster, producing herpetic keratitis [54], or may be an inductor for ocular manifestation of autoimmune diseases.

Several retinal complications have been reported after refractive surgery such as mild macular edema [55], worsening of myopic maculopathy [55], macular hemorrhage [55], retinal detachment and macular hole formation [55], mostly reported after LASIK refractive surgery, however their incidence is less when compared to intraocular surgery such as refractive lens-exchange and a clear pathophisiological link via biomechanical stress undergone during the suction/docking process in LASIK flap creation, or via excimer laser shock waves could not be established. Furthermore, laser-surgery patients presumably benefit from more frequent and complete follow-up appointments, which could artificially increase incidence of myopia-related complications after refractive surgey which are owed to the patient's myopia. In the case of retinal surgery for detachment or other pathology requiring vitrectomy, LASIK flap detachment has only been reported in a few cases [55], such as 69 months after LASIK surgery [55], with the risk being exceedingly low.

Unexpected events such as failure of the excimer laser during surgery have been reported. According to Büyükyildiz HZ [56], after uneventful flap creation, the laser platform failed during excimer ablation of the stroma at the 34% mark of the programme, refusing to fire. The flap was repositioned over the cornea and a technician was able to quickly resolve the issue [56]; the same ablation programme was loaded into the laser and performed to a piece of paper until the 34% mark, after which treatment was resumed and completed on the patient with excellent result of 20.16 (better than 20/20) vision at 6-month follow-up [56]. This raises the question of how to manage a hypothetical mechanical failure which cannot be quickly repaired since, firstly, due to high-cost of the platform it is unlikely the practice would have another comparable platform available just as a spare, and furthermore since the laser platform already performed part of the treatment, continuing the treatment with another laser-platform model or from another brand is untennable due to programming and performance differences. Basically, another identical laser should be quickly available or found, or the patient postponed for reintervention.

Justice and malpraxis litigation in refractive surgery

Refractive surgery's caractheristics of being an elective/optional vision enhancement surgery considered at the patient's behest in a private practice enviroment or provided by a large organization such as the military for professional activity requirements [17-18], together with the hype and expectation of a 20/20 or better vision from the usually young and socially-active patient significantly increase the burden on the physician when things do go wrong, exposing the clinician to litigation. Custer BL *et al.* reviewed data on malpractice claims related to refractive surgery [57], with the most common allegations formulated against the clinician or clinic being negligence in treatment or surgery (76%, 127 cases) [57] and lack of informed consent (49.7%, 83 cases) [57]. Only 35.3% of cases were unfavorable to the defendant, with the need for surgical reintervention or resulting corneal ectasia (keratoconus) most likely to favor the plaintiff [57]. Failure in preoperative screening and diagnosis of underlying conditions favored the defendant, while machine malfunction (8 cases, 4.8%) favored the plaintiff [57].

Most common patient complaints after refractive surgery were visual impairment, need for further surgery, night vission issues, corneal injury, and corneal ectasia. On the physician's side, Abbott RL. *et al.* reported that having a higher surgical volume [58] or a prior malpraxis claim [58] as factors increasing litigation risk even after adjusting for patient volume differences [58]. 10.1% of refractive surgery responders to the study reported experiencing a claim or lawsuit associated with PRK or LASIK refractive surgery. LASIK surgery was involved in 79.5% of claims *vs.* 6.45% PRK [58], owing to the popularity of LASIK technique and laser-platforms [58]. Additional predictor factors for litigation were physician's gender (male 93.6% [58]), more aggressive advertising, preoperative time spent with the patient and comanagement with optometrists, while bilateral same-day surgery was not associated with increased risk [58].

DISCUSSION

Laser-assisted refractive surgery is a surgical intervention, a permanent operative correction of optical reffraction errors subjected to literature-cited risk of complications. As such, first and foremost, care should be taken with regard to the patient's decision to undergo surgery, which should not be forced via marketing, peer pressure, or hyped presentation of the benefits. Once a surgical decision is taken, laser-assisted refractive surgery offers efficient correction and improvement in perceived quality-of-life with an excellent safety profile [19-23], and is successfully used both in a elective, private practice enviroment, and also for professional or career requirements such as for personnel serving in branches of the military where optical correction is deemed impractical (for example pilots). Technological factors such as utilising certain refractive-surgical platforms versus others do not pose statistical difference to the patient, with excellent results reported overall across different procedures such as PRK, LASIK, SMILE, FS-LASIK, Epi-LASIK.

The concept of respecting patient autonomy is critical when undergoing surgical assessment. The patient must be fully informed both on the possibility of surgical complications and also with regard to unwanted results such as photic phenomena (glare, haze, halos, rainbow glare) or the possibility of undergoing refractive regression postoperatively since individual variance exists in the postoperative healing process [42-47]. Photic phenomena are, unfortunately, an underlying possibility due to technical details such as the molecular ablation pattern of the femtosecond lasers [51-52], while the optical ablation area cannot cover any light situation of the patient with aberrations susceptible to occur in low light enviroments with high-contrasting punctiform light sources due to pupilarry diameter potentially exceeding the dimensions of the optical ablation zone, allowing stray light to refract differently in the transition area. Technological progress has been rapid in laser-assisted refractive surgery, with more accurate calculations, topographical personalised ablations profiles and artifical-intelligence aided keratoconus screening [33], aberrometry-infered measurements [53], advancement in angle kappa calculation [47], faster and more precise laser-platforms, newer procedures (Trans-PRK, SMILE, FS-LASIK, topografically-and-analitical-engine guided LASIK) and increasing standards in patient care. Performing novel crosslinking (CXL) protocols has greatly expanded the management of corneal ectasia, allowing surgery to obtain both optical correction and mechanical strengthening of the cornea, such as trough PiXL and NLO CXL protocols that combine

CXL with the UV excimer laser ablation. These technological benefits help the patient, and a complete preoperative assessment should inform the patient on therapeutic options available.

Autoimmune disease or systemic disease does not represent an absolute contraindication to refractive surgery [39], however a case-by-case decision process should be undergone together with the patient, and surgery should be timed in a moment of adequate control over the autoimmune/systemic afflicitons. Patients should absolutely be informed of possibly higher risk of postoperative complications firsthand [41], with respect to the principles of beneficence, non-maleficence and respect for autonomy [3]. Furthermore, anamnesis should be conducted with due dilligence, even in the abscence of ocular symptoms, as the reverse is also available, as in performing refractive surgery only to discover underlying autoimmune disease trough unexpected postoperative complications.

Obtaining adequate consent in the presence of complete information is essential, since the majority of litigation cases occur preponderently in the abscence of effective communication [57-58]. With respect to correct preoperatory patient selection and to professionalism in postoperative follow-up including complication management, refractive surgery is safe and effective. Despite this, a perfect refractive result cannot be guaranteed even in the presence of perfect ablative calculations, as there is individual variantion in the healing process and as such patients should be informed and understanting of the predictive limitations of the surgery.

In conclusion, refractive surgery satisfies the bioethical principles championed by Tom Beauchamp and James Childress of beneficence, non-maleficence, respect for autonomy, and justice [3-4]. The surgery is benefic both to the patient's goals and desires and to society by reducing the burden and lifetime-cost of optical correction [6, 14-15]. Using correct criteria for patient selection and adjustment of treatment in more borderline cases, the principle of non-maleficence is attained within the reasonable risk of the surgical intervention. With respect to patient autonomy, it is necessary to fully inform the patient on a wide range of possible complications or unwanted results, which most importantly must include the possibility of photic phenomena such as glare, haze, halos, or refractive regression and unknown individual variance in the postoperative healing process. Patients should also be reassured that in the unfortunate event of a complication, or even an unexpected event such as a technical equipment failure, therapeutic and contingency solutions are available, and their implications and prognosis should be clearly explained such as the possibility of requiring another surgical intervention. In borderline cases where the patient presents risk factors for refractive surgery, the decision should be taken on a case-by-case basis, weighing together with the patient the perceived benefits of the surgery and the possibility of ocular complicaitons; with the surgical intervention performed at a time of achieving control over the patient's other afflicitons. It is critical that the physician provides adequate patient discussion time to convey the above information, since physicians with a higher patient volume or previous claims by plaintiffs are especially suspeptible to litigation claims [58]. In case things do go wrong, as is the case with any surgical intervention that can eventually present complications in a particular case, having had spent the time necessary to fully inform the patient can maintain patient-physician trust, provide a positive enviroment where the patient attends follow-up and respects therapeutical treatment, increasing the odds of successfully managing the case for the benefit of both the patient and the practitioner. It is a mark of professionalism to perform surgery while minimizing risks, and when complictions do occur to diagnose them early and provide appropiate treatment in a professional manner, averting harm and dissatisfaction for the patient. The refractive surgeon must delicately balance the patient's judgement using medical criteria that "avoid reducing quality-of-life judgements to arbitrary personal preferences or to the patient's social worth" (Beauchamp and Childress) [3], satisfying the bioethical principle of justice. Refractive surgery presents a safe and effective solution for the correction of refractive errors.

Conflict of interest

The authors declare that they have no conflict of interest.

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