

THE GROWING BURDEN OF REFRACTIVE VICES AND REFRACTIVE SURGERY

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Abstract: Introduction: Refractive vices (myopia, hyperopia and astigmatism) decrease visual acuity and quality. This visual impairment is surgically treatable by refractive surgery.

Materials and Methods: The study's aim was to establish a clearer picture of current and future prevalence trends of refractive vices and the societal and medical role that laser-assisted refractive surgery is to play in this picture.

Results: The prevalence of myopia has increased alarmingly due to modern life factors such as long study hours and inadequate indoor light in lieu of outdoor sufficient light, to the point that myopia is set to become the de facto normal; astigmatism also presents lower rising trends, while hyperopia's prevalence remains the same. Refractive surgery was most successful in correcting myopia and myopic astigmatism by Trans-PRK, SMILE and variants of LASIK. Personalized corneal reshaping techniques such as topography-guided LASIK (Alcon Contoura, PhorCides) or Trans-PRK (SCHWIND) allow absolute astigmatism correction by reshaping the cornea to exactly match the individual's optic system. In high myopes LASIK can achieve up to -18.5 Diopters correction provided sufficient corneal tissue is available; otherwise phakic intraocular lens implants are an excellent and safe alternative. The implantable collamer lens (ICL) is placed in front of the natural lens and can be combined with laser surgery to achieve huge corrective potential (bioptics surgery). For hyperopia LASIK is most established and reliable with Trans-PRK suitable for only minor correction.

Conclusion: Laser-assisted refractive surgery has advanced greatly with a multitude of techniques to cater safely and effectively to each scenario. In the coming myopic world this surgery will offer major medical and societal benefits.

Keywords: refractive surgery, refractive vices, myopia, prevalence, vision improvement.

INTRODUCTION

Refractive errors are a leading cause of treatable visual impairment [1]. Treatment options include optical correction via glasses or contact lenses or the use of special lenses with the goal of slowing the evolution of the refractive error. Refractive surgery is an encompassing term for various types of surgical interventions that aim to surgically correct the refractive error of the patient [1]. This surgery can be necessary in a multitude of cases, for example for correcting significant imbalances between the refractive power of one eye and the other; this imbalance could put the patient at risk of developing amblyopia or permanent visual impairment in the weaker eye due to neuroadaptation favoring monocular vision in the good eye and dismissing the "wrong image" from the

weak eye. While amblyopia can be corrected up to a point using optical correction, when the difference is too great between the eye's surgery is needed to apply the correction. However, the most common desire from refractive surgery is surgical correction of a refractive vice so that the patient is not required anymore to wear glasses or contact lenses. While an outdated view would be that this is in effect a cosmetic surgery [1] this couldn't be farther from the truth with the intervention's benefits extending to quality of life, working ability, improved daily working performance [1] and socio-economic benefits in performing a single intervention well *versus* a lifetime of corrective devices [2]. In certain professions, for example military service as a pilot, this surgery can become de facto required [3-5] and provides critical benefit to the performance capabilities of the individual [4]. In this endeavor refractive surgery is

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most favorable since the closer the correction is applied to the corneal surface, the more increased is the quality of vision with the added benefit of a greater corrected field of view; thus, glasses are inferior to contact lenses which interface atop the corneal surface. Laser-assisted refractive uses an extremely precise laser to reshape the corneal surface achieving an absolute correction of both common, lower-order refractive aberrations (myopia, hyperopia, and astigmatism) [1], as well as high-level aberrations (HOAs) which can also decrease quality of vision [1,6]. For these purposes laser-assisted refractive surgery requires a stable optical system (no refractive power change in the last one to two years) and a healthy cornea with enough thickness. If the asked-for correction is too great and would require too much corneal tissue to be ablated or in the presence of other contraindications, other types of refractive surgery enter the stage such as intraocular lenses [1] which can either replace or augment the existing natural lens of the patient; these are especially helpful in highly myopic patients. Due to its simplicity, effectiveness and safety [1,7] laser-assisted refractive surgery has become the most common refractive surgical technique [1] and has become synonymous with “refractive surgery” in the layman’s view. This study seeks to explore the current and future role of laser-assisted refractive surgery in today’s and tomorrow’s world.

MATERIALS AND METHODS

A wide-targeted search of Clarivate Web of Knowledge and PUBMED databases was performed for papers within the last 15 years concerning prevalence of myopia, hyperopia, astigmatism with the aim of establishing a baseline analysis of their prevalence. Furthermore, a similar Web of Knowledge and PUBMED search was performed for refractive surgery papers addressing the treatment of myopia, hyperopia and astigmatism. The study’s aim was to quantify what role does refractive surgery play in the treatment of prevalent refractive errors and what future trends in refractive surgery could look like.

RESULTS

Ocular growth is influenced by visual experience factors [8-10]. Reduction in image quality and defocused image formation lead to changes in axial eye growth. Axial growth produces a forward focusing, unclear image (myopia). Shortened axial length produces a back-focused image (hyperopia).

Changes in corneal surfaces and lens aberrations lead to the existence of more refringent meridians which defocus the resulting retinal image (astigmatism). Many studies have researched the impact of modern society on the development of the human eye. It is now widely accepted that myopia is an actual and growing epidemic [9] especially affecting the young. While the European Eye Epidemiology (E3) Consortium found a peak incidence of myopia in European 25–29-year-olds at 47.2% [10], this already high prevalence pales in comparison to the staggering 80-90% in East and Southeast Asia [8]. Myopia, reported as affecting nearly 30% of the world population irrespective of age [11-12] in 2020, is growing explosively in prevalence and is set to affect 50% of the world’s population [13] by 2050, or about 5 billion people by 2050 [13]; with 1 billion people having high myopia [13]. In essence myopia is soon to become the new normal. This is linked inextricably to modern societal changes: studies have confirmed rising education levels and close-up work and reading, together with lack of indoor light instead of powerful natural outdoor light as decisive factors in the rise of the myopia endemic [8, 14-16]. For example, a 1969 study of Inuit people in Alaska observed only 2 adults out of 131 had myopic eyes [14]; among their children however almost half presented myopia [14]. The first found culprit was education and intense book reading: 15-year-olds in the United Kingdom spent on average 5 hours on homework, 6 hours in the United States and 14 hours in China’s Shanghai [8,15]. Indeed, in Asia in particular the education systems are hypercompetitive, demanding more and more time spent studying. In China 90% of young adults are myopic [8] and in South Korea 96.5% of 19-year-olds are too [8]. However more recently another culprit was noted: a study in California noted a strong association of time spent outdoors as a protective factor for myopia [16]. Further research, as summarized by Dolgin E. [2], has confirmed that the lack of powerful light levels typical to outdoor activity is another contributing factor for myopia [2,16]: indoor exposure as in indoor light or electronic screens does not produce adequate light for the human optical system. In the adversity of high amounts of short-sighted work and insufficient light the eye maladapts growing its axial length leading to more and more myopia.

Hyperopia prevalence in school-aged children its prevalence was not influenced by gender, family income or parental schooling [19]. Hyperopia was found to affect 34.7% of European individuals [9] with age-standardised prevalence of 25.2% [9]; hyperopia was more prevalent in higher age groups of middle age

or older age (31% 95% confidence interval CI) [9] and more prevalent in European women (2.5% difference, $p=0.04$) [9]. Other studies have reported a similar increase of hyperopia in later aged individuals [9,19].

Astigmatism prevalence in European populations was found to be more or less the same throughout the age brackets by the E3 Consortium study (23.9% age standardized 95% CI 23.7-24.1) [9]. Astigmatism was more prevalent in European males (3.8% difference, $p=0.001$) [9]. Other studies have reported a link between higher prevalence of astigmatism in Asian preschool children [17] and electronic screen exposure, correlating with daily screen time and total exposure years [17,18]. A study of the United States population by Valluru G *et al.* found an increase in astigmatism prevalence between 1970s and 2000s data [20] ($p < 0.001$); age adjusted this difference decreased to 23% *versus* 23.7% [20]. This study reported an increase of against the rule (ATR) astigmatism from 36% in 1970s to 41% in the 2000 and summarized that ATR astigmatism increases with age [20]. This study also highlighted the growing burden of increases in myopia, much higher than astigmatism [20]. Overall astigmatism prevalence is also increasing but considerably slower than myopia [20]; a link was also established to the myopic boom in children [17, 18].

A literature-wide analysis of refractive surgery techniques and their results was performed. Laser-assisted in-situ keratomileusis (LASIK), transepithelial keratectomy (Trans-PRK) and the older photorefractive keratectomy (PRK) and small incision lenticle extraction (SMILE) were the most commonly encountered techniques.

For LASIK the largest study by population found was a multicenter retrospective survey performed by Kamiya K *et al.* of 78248 eyes of 39727 consecutive patients undergoing refractive surgery in Japan [7], 90.9% of which underwent LASIK surgery. 95.9% (67512 eyes) were reported to achieve 20/20 or better vision uncorrected; considered the normal, healthy vision level; concerning safety 99.5% (69987 eyes) achieved 20/20 vision using optical correction after surgery; as such correction only added a further 3.6% (2475). Remarkably an outstanding 98.3% (69176 eyes) were within ± 1.00 Diopter (D) of the ideal plano correction (0 D) [7]. Other authors have reported at least 16 million LASIK procedures have been performed worldwide [21]. LASIK surgery is a two-step approach where first a corneal flap is created, followed by corneal stromal ablation using an ultraviolet excimer laser [21].

Most of the encountered surgical complications were attributed to the use of previous older technologies of microkeratome flap creation [21]; today this flap is created using a highly precise femtosecond infrared laser in a matter of seconds [21, 22]. Today's LASIK is synonymous with femtosecond LASIK (FS-LASIK). Sandoval HP *et al.* meta-analysis revealed no statistical differences for 20/20 and 20/40 uncorrected visual acuity (UDVA) data regardless of the modern LASIK surgical platform used [21]. In aggregate the weighted percentage of eyes with UDVA of 20/20 or better was 90.8% (55689/61331) [21] with the landmark PROWL-1 study reporting UDVA of 20.20 or better in 97% of right eyes, 98% of left eyes and 99% of either eye [21, 23]. Loss of two or more lines of corrected distance visual acuity (CDVA) is an established term for surgical failure in visual result. Loss of 2 or more lines CDVA was highest in eyes treated for hyperopia *versus* myopia (2.13% *versus* 0.95%, $p < 0.01$) [21, 23]. The refractive accuracy to within ± 1.00 D of ideal plano target (0) was higher than 80% in all studies [21, 23], above threshold 75% established by the Federal Drug Administration (FDA) [21, 23]. In 77% of eyes the mean spherical equivalent, a measure of combined spherical and cylinder refractive result (spherical + $\frac{1}{2}$ cylinder) was within ± 0.25 D of ideal plano (0 D). SE results were decreased for higher myopes and hyperopic patients [21,23]. 98.7% of patients were satisfied or very satisfied with their LASIK surgery [21, 22-24], similar to PROWL-1 and 2 trials [23, 24]. LASIK also reliably achieved results in high myopia [25] and high hyperopic astigmatism [26], however with more difficulty due to the extensive refractive pathology. In high myopia Güell JL *et al.* found more accurate predictability up to -12.00 D of correction [25], while Reinstein DZ. Reported good results in high hyperopic LASIK up to +8.33 D with the MEL 80 system [26]; results were overall lower *versus* traditional myopia/hyperopia correction with 76% of eyes achieving 20/20 uncorrected vision, 67% of eyes within ± 0.5 D of plano target and 89% within ± 1.00 D; SE within ± 0.5 D in only 50% and within ± 1.00 D in 76% of eyes. Next-generation developments in LASIK are the creation of patient-tailored highly customizable topography-guided laser ablation profiles that seek to also correct minute visual imperfections that arise higher order aberrations. The Layer Yolked Reduction of Astigmatism (LYRA) Protocol has been extensively presented by Motwani M *et al.* in a series of papers [27-29]. Using Alcon Contoura surgical planning software higher-order corneal aberrations such as trefoil, quadrafoil and coma can be corrected

together with lower-level astigmatism aberration, resulting in a supraphysiological cornea devoid of aberrations (LYRA part 1) [27]. The Contoura software was also successfully used to retreat previous inadequate astigmatism correction (LYRA part 2) [28] and to fully eliminate astigmatism from 48 eyes out of 50 (LYRA part 3), achieving 100% 20/20 vision and 80.85% supraphysiological 20/15 (150%) vision. Other developments are the Phorides analytical engine which could improve visual results in more niche cases such as enhancement with LYRA surgery [30, 31].

For phakic intraocular (IOL) lens implantation Kamiya K *et al.* Japan study followed a large population [7] and reported 94.1% (890 eyes) achieved 20/20 uncorrected vision and 98.8% (935 eyes) 20/20 corrected vision; 96% (908 eyes) were within ± 1.00 D of ideal plano refraction (0 D). The results were slightly lower than LASIK at 95.9%, 99.5% and 98.3% within ± 1 D respectively [7].

Transepithelial photorefractive keratectomy (Trans-PRK) is a novel version of the established photorefractive keratectomy (PRK) technique. In the traditional PRK the epithelium is removed using an alcohol-based or mechanical method which could lead to increased postoperative pain, corneal haze and irregular epithelial healing [32]. Trans-PRK advanced by using the excimer laser to remove the epithelium, creating a single-laser solution that first removes the epithelium and then applies the stromal refractive correction [32]. The procedure is shorter, more precise, minimizes corneal dehydration [32] and together with application of mitomycin-C leads to better refractive predictability and results over time [32]. Chang JY *et al.* metaanalysis reported literature-favorable efficacy and safety of Trans-PRK for myopic and high myopic patients [32]. Trans-PRK lead to a slight overcorrection *versus* under-correction in the LASIK group and better overall uncorrected distance visual acuity [32]. Refraction at 12 months of follow-up were better and more predictable in Trans-PRK patients. Wavefront guided Trans-PRK showed more predictable astigmatism correction axis than wavefront optimized Trans-PRK for astigmatism values over 1.75 D. Jiang J *et al.* Analysis found a higher incidence of total higher order aberrations (HOAs), spherical and vertical coma after Femtosecond-LASIK *versus* Trans-PRK [33]. The authors highlighted other reports that FS-LASIK flap creation could induce HOAs [33]. Sabhapandit S *et al.* compared studies on Trans-PRK treatment of hyperopia finding 80% predictability in moderate hyperopia and 90% in low-grade hyperopia [34]. Higher hyperopia was

more linked to events of regression [34] with rates of 0.004 D/month up to 1 year postoperative reported by other authors [34]. The authors noted that so far LASIK and traditional PRK had achieved satisfactory results in hyperopia; while Trans-PRK did provide benefit, it is most successfully used in mild to medium hyperopia [34]. High hyperopia and high hyperopic astigmatism are domains where LASIK is to be used [26]. Kornilovskiy IM *et al.* reported successful secondary emission of UV at the corneal stroma in Trans-PRK [35], thus allowing Trans-PRK surgery to photoactivate riboflavin - a hybrid Trans-PRK and Crosslinking surgery [35]. This is highly advantageous due to elimination of additional UV load on the cornea which is already exposed to oxidative stress from the laser photoablation itself [35]. Ezzeldin M *et al.* analysis of reported combined excimer-laser surgery with riboflavin crosslinking [36] highlighted several studies using PRK and novel studies using topography-guided Trans-PRK with crosslinking for keratoconus treatment [36]. More specifically Kanellopoulos AJ investigated the use of topography guided Trans-PRK to perform an initial corrective surgery that flattens the cornea in keratoconus patients, similar to a hyperopic correction in a healthy cornea [37], with the purpose of redistributing biomechanical forces on a more regular and better resisting corneal shape [37]. Afterwards crosslinking was performed for 10 minutes with riboflavin solution 0.1%; applying the crosslinking immediately after laser-ablation minimizes stromal haze formation as the crosslinking procedure effectively destroys damaged keratocytes as deep as 300 μ m, preventing them from starting a fibrosis process [37]. Kanellopoulos AJ noted a lower ectasia progression in treated patients with fewer progressing to penetrating keratoplasty and visual benefits from the Trans-PRK correction [37]. This emerging field of innovative field of combined Trans-PRK refractive correction and crosslinking for achieving stability of disease in keratoconus patients opens up a new frontier in keratoconus treatment [36,37]. Further evolutions of the Trans-PRK technology are next-generation corneal wavefront-guided calculation software providing a personalized-for-the-optical-system surgery with improvement in prediction of astigmatism correction axis and fewer corneal aberrations [38]. Other advancements concern the laser-delivering technology such as smart pulse technology which greatly accelerated the postoperative recovery procedure; 82% of patients achieved 20/32 uncorrected vision or better immediately after the surgery [39].

Small incision lenticule extraction (SMILE) uses

a femtosecond laser exclusively to carve out a portion of the corneal stroma which is then excised through a very small laser-made incision [40]. Femtosecond lenticule extraction (ReLEx) uses a different mechanism for lenticule extraction that cannot extract through a small incision. SMILE has superseded the previous ReLEx [40] and similar techniques to become a highly-performed surgery for myopia and myopic correction due to the single-laser solution and excellent results when compared to traditional LASIK surgery [40,41]. Zhang Y *et al.* systematic review compared SMILE with FS-LASIK throughout 11 studies which involved 1101 eyes; 48.32 % (532) underwent SMILE and 51.68% (569) underwent FS-LASIK [40,41]. No statistical differences were found for spherical equivalent ($p=0.72$), safety (eyes losing one or more lines of CDVA) ($p=0.69$), eyes achieving 20/20 or better vision ($p=0.35$) or refractive spherical equivalent within ± 1.00 D ($p=0.70$). One of the largest studies on SMILE found was Payne CJ *et al.* 1 year outcome and corneal higher-order aberration assessment of 405 eyes treated with SMILE. 79% of eyes had uncorrected vision of 20/20 or better at 1 year [42]; 91% vision of 20/25 or better; Safety was excellent with only 0.3% lost two or more lines of CDVA at 3 months postoperative and no further loss at 1 year. Spherical equivalent accuracy was within ± 1.00 D in 94% and 97% of eyes (3 months and 1 year postoperative), with ± 0.5 D at 84% at both follow-up periods. The possible drawback of SMILE rests in not producing a surface correction: Payne CJ *et al.* reported significantly increased total of higher-order aberrations pre-operatively to 12 months ($p<0.001$) [42] with increase in the spherical components ($p<0.001$) and decrease in vertical coma ($p<0.001$); no change in horizontal coma or trefoil. Astigmatism correction overall was excellent with a trend for under correction by 13-17% [42]. As such since SMILE only treats the corneal stroma, patients with decreased vision also due to higher order aberrations or irregular corneal shape should be candidates for topography-guided LASIK [27-29]. However, for myopia correction SMILE results were overall excellent with the procedure simpler, safe and effective. Wong AHY *et al.* [43] highlighted benefits to the ocular surface in SMILE surgery, with patients suffering less corneal denervation and better corneal sensitivity *versus* FS-LASIK [43]. Wang Y. and Ma J. analysis [40] highlighted that future research is needed towards correcting hyperopia or high myopia with SMILE; for the first hyperopic surgery presents disadvantages in refractive stability *versus* other lenticule techniques such as ReLEx [40]; and for the

latter SMILE is prone to under correcting in high myopia [40].

DISCUSSION

The world is changing as it becomes more educated and technologically advanced and from a refractive point-of-view this change is worsening eyesight by explosively increasing the prevalence of myopia [8] and myopic astigmatism [17]. Hyperopia and hyperopic astigmatism prevalence data has not changed significantly. To aid in treating this myopia epidemic lifestyle adjustments should be sought such as promoting a more health life-study balance, exposure to outdoor light and adequate indoor light [10]. Certain medications have also been associated with myopic development and progression such as systemic retinoids used for their dermatological therapeutical effect [45]. Retinoids are potent proliferation modulators with known side effects such as lipid disorders, dry skin (keratinization), photosensitivity and also myopia onset which should be followed and treated, eventually benefiting from refractive surgery [45].

However even with these changes it is likely the prevalence of myopia will increase and as such concrete treatment options should be assessed. Growing awareness, early diagnosis and advancement in spectacle lenses and orthokeratology are excellent for progression control [46]. Once the axial length growth is successfully stopped another solution could greatly benefit both the patient and society: refractive surgery. Laser-assisted refractive surgery is a proven method in treating a wide variety of refractive vices; the quality of the resultant correction greatly improves vision by not only correcting the lower-order refractive error but also reducing higher-order aberrations which affect quality of vision such as contrast sensitivity. Together with the benefit of spectacle independence these advantages enhance quality of life and work performance and lowers the societal burden of successive optical correction prescription [2]. Urgent effort must be made to provide valuable early life advice such as balancing study time with outdoor activity, the necessity of adequate light levels when studying or working and so forth [46]. Early diagnosis, therapeutical correction using spectacles or special myopia spectacles and other therapeutical agents are cornerstone therapeutic acts which could slow disease progression. After achieving refraction stability and successful refractive vice control, the eventuality of recommending an assessment for refractive surgery makes sense. Refractive surgery could provide tangible

benefit to a wide variety of patients; currently the best results are with myopia, astigmatism correction and mild to moderate hyperopia. An early screening and follow-up system could vitally detect patients at risk for amblyopia; if need be of surgical correction, then the intervention effectively protects against developing neuro-adaptation amblyopia of the weaker eye, could restore (at least partially) binocular vision and greatly improve the quality of life. Taken as a piece of a larger, comprehensive strategy, refractive surgery is an ever-advancing tool for improving the quality of vision and life.

In conclusion, the burden of refractive vices is continuously growing due to various causes and conditions including side effects treatment such as systemic retinoids use, while refractive surgery is to play an important final step in the treatment. Refractive surgery improves quality of life by significantly improving quality of vision; by measured visual acuity and most importantly also by reducing higher-order aberrations and improving contrast sensitivity. Technological and medical advancement have created excellent safety and efficacy for a variety of laser-assisted surgical techniques, all the while the need for refractive correction is rising due to the myopia and myopic astigmatism boom. Overall comprehensive prevention and treatment strategies are required to protect useful vision while improving quality of life.

Conflict of interest

The authors declare that they have no conflict of interest.

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