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Presbyopia – epidemiological background, pathophysiology, and treatment methods, including laser refractive surgery

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HIGHLIGHTS

The work was based on available literature on presbyopia, current articles in the PubMed and Medline database.

ABSTRACT

Presbyopia is the inability to see small things up close, usually occurring after the age of 40, associated with loss of accommodation, which results in dependance on glasses when working up close. There are many different methods of correcting presbyopia, but it is still difficult to restore the status from before disease onset. The article describes the epidemiology, pathophysiology and non-surgical and surgical methods of treating presbyopia, with particular emphasis on corneal, scleral and intraocular refractive methods related to lens replacement.

Key words: presbiopia, refractive surgery, multifocal intracocular lens, scleral procedures, presbymax, presbyond

INTRODUCTION

Presbyopia is the inability to see small things up close, usually occurring after the age of 40, associated with loss of accommodation, which results in dependance on glasses when working up close [1]. There are many different methods of correcting presbyopia, but it is still difficult to restore the status from before disease onset [2].

EPIDEMIOLOGICAL BACKGROUND

The first symptoms of this condition usually appear around the age of 40, in a group of professionally and economically active people. However, they do not properly correct vision defects due to poor availability of services and a lack of awareness [3]. Even in developed countries, the number of presbyopes who do not use glasses is statistically high. In a study in the United States, 13.6% of respondents presented with symptoms of near vision impairment (PNVI; vision worse than 20/40), and 25.9% of subjects presented with functional near vision impairment (FNVI; moderate difficulty with reading newsprint or near work) [4]. It is said that presbyopia affects approximately one billion people in the world [5].

The Korean national health and nutrition survey provided interesting results in this respect. The study included 21,415 people aged between 20 and 49 years. 81% of them were under 40 years of age, and 1,621 underwent a refractive surgery. In a period of 8 years, the number of refractive surgery procedures performed increased by 10%. Young women living in cities, with higher education and earnings, have always constituted a high percentage of people in society undergoing refractive procedures. Over the course of 8 years of the study, this disproportion started to change and disappear, and increasingly more social groups began to undergo these surgeries. The study concluded that the number of people from different groups undergoing refractive surgery was increasing, regardless of their status or gender [6].

Another Korean study examined changes in the clinical practice concerning refractive surgery over a 10-year period. The respondents were asked 59 questions. The survey concerned the preferred method of refractive surgery, the excimer laser, and the method of presbyopia correction. 50 surveyed members of the Korean Association of Cataract Surgeons responded out of 742 who received the survey. 54% of respondents were in their 40s, and on average, they performed 53 refractive surgery procedures per month. The most frequently used device was VISX S4, followed by: EX500, Allegretto wave Eye-Q, and AMARIS 750. The most frequently performed procedure was superficial ablation, accounting for 15% of the cases in 2005, versus 40% in 2015. The popularity of the LASIK procedure decreased from 48% in 2005 to 20% in 2015. The number of respondents performing presbyopic procedures increased from 30% in 2007 to 76% in 2015. A femtosecond laser was used in 80% of LASIK procedures [7].

PATHOPHYSIOLOGY

There are several theories explaining the pathophysiology of presbyopia. The well-known Helmholtz theory assumes that the ciliary muscle contracts and relaxes the fibers of the ciliary band, which causes the anterior lens bag to bulge [8]. Another opposing theory proposed by Schachar assumes that contraction of the ciliary muscle causes an increase in tension of the equatorial fibers of the ciliary band, and relaxation of the anterior and posterior fibers of the ciliary band, causing a subsequent steepening of the central part of the lens [9].

Coleman's chain theory assumes that contraction of the ciliary muscle causes an increase in the pressure gradient between the vitreous compartment and the rear chamber filled with liquid, and in consequence, bulging of the front part of the lens [10].

TREATMENT METHODS

In the present paper, we will classify the methods for treating presbyopia into surgical and conservative ones. Surgical methods will then further be classified into those involving the cornea, sclera, or lens.

NON-SURGICAL TREATMENT METHODS

Glasses are the simplest method for correcting presbyopia. Available variants include single-focal, bifocal and progressive lenses. Single-vision lenses are the cheapest option, enabling a patient to read comfortably up close.

In some cases, presbyopia is accompanied by another vision defect, e.g. farsightedness. In this case, a patient needs 2 pairs of glasses for different distances. Then, bifocal glasses can be a useful solution, as they eliminate a need to constantly switch between glasses, but they are more expensive [11].

Bifocal glasses do not solve the problem of seeing at intermediate distances, which is addressed by progressive glasses. They can be used for all distances, but they are also the most expensive option.

Contact lenses can also help people suffering from presbyopia. They can be chosen to create monovision, with one eye set for far, and the other for near sight correction. This is associated with a deterioration in contrast sensitivity [12]. Another option is offered by the multifocal contact lenses, which, due to their design, allow each eye to work at all distances.

The U.S. Food and Drug Administration (FDA) has approved VUITY drops for the treatment of presbyopia. This is a solution of pilocarpine hydrochloride 1.25%. The

drug was approved on October 28, 2021, based on the GEMINI 1 and GEMINI 2 studies. During the studies, the name AGN-190584 was used. 750 participants between 40 and 55 years of age participated in the study (375 received VUITY) lasting 30 days. Both studies demonstrated greater gain of 3 lines or more in mesopic conditions for near with best distance correction compared to controls without loss of more than one line for distance. The recommended dose is one drop in both eyes, the dose can be repeated after 3 h. The product is packaged in 2.5 and 5 mL container [13]. The effectiveness of this method was confirmed in another study called VIRGO, which involved 230 participants and 114 received the drug [14].

It should also be added that the FDA approved QLOSI drops for the treatment of presbyopia on October 17, 2023. It is a 0.4% pilocarpine hydrochloride solution. After twice administration at an interval of 2 h, the effect lasts up to 8 h. The drug was approved by the FDA after examining 613 patients (309 of whom received QLOSI) in the NEAR-1 and NEAR-2 studies. The medicine is packed in a carton box of single use vials [15, 16].

SURGICAL TREATMENT METHODS

Corneal procedures

Monovision is a situation in which one eye focuses on closer and the other at the farther distance. This effect can be achieved by programming the refractive surgery procedure. This solution to the problem of presbyopia is popular and quite attractive for patients. In this area we distinguish classic monovision, mini-monovision, and multifocal corneal ablation. More recent solutions include procedures forming an intracorneal lenticule. Research shows that monovision is a good solution for presbyopes. Treatments lead to the desired visual acuity, patient satisfaction and independence from glasses [17].

Studies were conducted on the quality of vision in patients post presbyopia correction by the LASIK surgery. A retrospective study analyzed 54 eyes of 27 patients who underwent presbyopia correction by achieving aspheric micro-monovision. One year after presbyopia correction, no differences were found in the modulation transfer function (MTF), the Strehl index and OSI. Postoperatively, the near contrast perception improved and accommodation range. The patient questionnaire showed subjective improvement in vision [18].

An interesting prospective study was conducted by Fu et al. The aim was to examine visual acuity in patients after the PresbyMax treatment in the monocular mode. 28 eyes of 18 patients were analyzed. The average age was 50.4 (±5.6) years. The examination was performed 1 day, 1 week, 1 month, 3 months and 1 year after the procedure. The aberrations were analyzed by a Hartmann-Shack wave sensor. One year after the examination, 100% and 94.4% of the subjects achieved binocular vision without glasses and near vision of 20/25, respectively. At the very end of the study, higher-order spherical aberrations were greater than before the procedure. No major differences were found between MTF, OSI or the Strehl index. There was a transient reduction in MTF and OSI in the nondominant eye. No significant differences between the nondominant and dominant eyes were found, except for horizontal coma and spherical aberration. The conclusions are that this method is safe and effective. A short-term reduction in image quality occurred with bilateral ablation [19].

In refractive surgery, the most commonly used method for presbyopia correction, presbyond LBV (Laser Blender Vision) treatment, uses a non-linear ablation profile and micro-monovision in the nondominant eye. Micro-monovision is of the order of -0.75 D to -1.5 D, enabling a reduction in the symptoms accompanying traditional monovision. Spherical aberration is so low that it does not cause visual impairment, but is sufficient to increase the depth of field for clear vision [20]. This results in a high rate of the post-treatment satisfaction.

Luger and colleagues analyzed the results for 66 eyes that underwent presbyopia correction surgery (PresbyMax). The preoperative corneal curvature was between 40 D and 48 D, and neither eye had previously undergone refractive surgery. In all cases, pachymetry readings always exceeded 500 µm. Preoperative visual acuity was 0.1 logMAR for distance and 0.2 logRAD for near vision with a correction of +2.5 D, or better. The results showed that after one year 70% of patients could see 0.1 logMAR or better without glasses, and 84% could read 0.1 logRAD without correction. The visual defect after surgery was usually -0.47 (±0.44) D and stabilization was achieved after 6 weeks [21].

All studies on Presbyond LBV lenses included in review from this year indicate that this aspherical micromonovision protocol is a safe procedure in terms of preserving contrast sensitivity in the treatment of myopic, moderate, and hyperopic presbyopia [22].

Scleral procedures

The first historical procedure was the anterior ciliary sclerotomy introduced by Thornton, which was a modification of the radial incisions (radial keratotomy) used by Fyodorov in the treatment of myopia. In this case, the incisions are made not in the cornea, but in the sclera above the ciliary muscle. This aims at enlarging the space between the lens and the ciliary muscle to increase the tension of the ciliary band and improve the ability to accommodate. Accommodation improved slightly, its amplitude increased by 0.8 D, and a shift of the ocular power towards myopia of approximately -0.5 D also occurred [23].

Scleral implants are based on the Schachar accommodation model. He explained that a reduction of the space between the lens and the ciliary ring causes a change in anatomical parameters, which results in development of presbyopic symptoms. This is a model supported by a significant body of experimental evidence. The implants, made of PMMA, were implanted between the sclera and the ciliary body. They expanded the space between the ciliary body and the sclera, which resulted in improved accommodation. Unfortunately, in some cases the procedure was also associated with complications, such as anterior segment ischemia. This is a serious complication, which led to the gradual discontinuation of this procedure, as the benefit in the form of improved near vision is disproportionate to the risk [23].

Currently, research is underway on the new VisAbility Micro-Insert implant, which is implanted 3,000–4,000 μm behind the limbus, at a depth of 400 μm, under general anesthesia. The results of the first 24-month observations were presented in 2013. The aim of the implant is to lift the sclera and ciliary muscle, thereby narrowing the circumference of the ciliary rim. The analysis covered the results for 80 patients. Before and after the surgery the respondents were asked to evaluate quality of their vision, using the following words: great, acceptable, and poor. 73% rated their vision as acceptable, with 99% of patients reporting it was acceptable for distance tasks. Patients evaluated their vision as acceptable when reading a newspaper in 4% and 76% of the cases before and after the surgery, respectively. The FDA conducted a study and found that in 75% of cases implantation of the 1st generation VisAbility Micro-Insert implant was associated with implant displacement or dislocation. Of course, this procedure is not free from more serious side effects, such as anterior segment ischemia, erosion, subconjunctival hemorrhage, infection and endophthalmitis [23].

By creating laser scleral microporation (LSM), the eye is rejuvenated and its natural ability to accommodate is restored. As the aging process progresses, changes occur in the lens, ciliary muscle, ciliary band, eye stiffness, uveal membrane and vitreous body, which play a role in the loss of accommodation and the development of presbyopia symptoms. During the procedure, the laser creates micropores in the sclera, which is intended to reduce its stiffness, increase its elasticity, and thus reverse the symptoms of presbyopia. The treatment produces a minimal inflammatory response [24].

A study on laser scleral ablation was conducted by Lin in 1998. According to him, the instability of radial incisions was related to their rapid self-healing. This problem was solved by removing a fragment of sclera that was 500–600 μm deep, of 4,500 μm by 600–700 μm. The results after 2 months showed an increase in accommodation by 2 D. It is assumed that this could be related to a reduction in the thickness of the anterior chamber and a shift in the visual system power in the negative direction [23].

Laser microexcision of the sclera is the last method we would like to discuss here, and the only one that underwent phase 3 clinical trials. The procedure with the ER:Yag ACE laser (scleral laser anterior ciliary excision) is based on the theory that presbyopia is not a refractive error or loss of accommodation, but rather involves age-related limitations and loss of the eye's mechanical, structural, cellular and physiological functions. The laser creates a network of 600 μm micropores in the sclera to 85–90% of its depth. The procedure is performed under local anesthesia and takes 10 min per eye. It improves the scleral plasticity leading to better accommodation during the contraction of the ciliary muscle [23].

Implantation of phakic lenses

The purpose of implanting the phakic multifocal intraocular lenses in people with their own lens is to correct the vision defect, allowing them reading without an additional aid of glasses, while sparing the lens. The pre-surgery status can be restored at any time by removing the implant. This method has certain limitations, and manufacturers are constantly developing new methods and solutions for lens production, as well as improving materials from which they are made.

Tests were carried out in 16 eyes of 8 patients, in whom visual acuity at various distances, refraction, endothelial cell density, anterior chamber depth, corneal topography, white-to-white parameter, pupil size in mesopic conditions, and intraocular pressure were measured. Then, the patients had a new diffractive lens implanted and tests were performed 4 weeks after surgery. 9 of 16 eyes were emmetropic, with a visual acuity of at least 0.8. No changes in pressure or endothelial cells occurred. The patients were satisfied with the procedures. All patients achieved full near visual acuity without the need to use reading glasses. Phakic lens implantation is a safe method with a high degree of patient satisfaction [25].

Baikoff conducted a study in 55 eyes of 33 patients (12 men, 21 women) with a multifocal foldable lens implanted into the anterior chamber. The refractive error was between +5.0 D and -5.0 D, and the near vision increase amounted to +2.5 D. The uncorrected acuity was 0.6 or better for distance and 3 or better for near vision. The lenses were explanted in 4 patients. The patients' uncorrected distance visual acuity improved to 0.78 (±0.20) for distance and the mean Parinaud uncorrected near acuity was 2.3 (±0.6) [26].

Multifocal pseudophakic intraocular lenses

By implanting a multifocal IOL after removing the cataract, we aim to achieve an effect in which the patient will not use glasses for both distance and near vision and with this to correct definitely presbyopia.

Nijkamp et al. conducted a study on patient satisfaction and test results after multifocal lens implantation. Results after

single-focal and multifocal lens implantation were compared. The implanted lens was monofocal in 75 patients and multifocal in 78 patients. The tests were conducted 3 months after the surgery and focused mainly on near vision acuity. On the next stage, a survey was conducted concerning satisfaction, dependence on glasses, and general vision-related functioning. The results showed that near vision without correction significantly improved in the patients after multifocal lens implantation. In a satisfaction survey, the patients post multifocal lens implantation assessed their vision as 1.6 before surgery and as 2.9 post surgery (on a scale of 1–5), and they did not use reading glasses at all (42.7%), or only occasionally. In the case of single-focal lenses, 21.6% did not use glasses for near vision, or "only now and then". Distance correction was not needed in 75% of the cases with multifocal lenses and in 46.2% of the cases with single vision lenses. Impaired vision and halos were reported fewer by the patients after implantation of mono-focal lenses. The final level of satisfaction was similar. The quality of near vision correction was strongly correlated with patient's satisfaction [27].

CONCLUSION

In this article, we attempted to briefly describe the methods for presbyopia correction. This topic is very broad, and researchers are still trying to discover the ideal procedure for treatment of this problem. Each has its advantages but is also associated with specific complications. Statistics prove that patients are satisfied with these treatment methods; although, of course, there will also be those who, despite the efforts, will not be contented with them. Fortunately, there are many different methods to correct this problem and the surgeons can offer many solutions to their patients.

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