ORIGINAL ARTICLE

Efficacy and safety of iris-supported phakic lenses (Verisyse) for treating moderately high myopia

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ABSTRACT

Aim To evaluate efficacy and safety of iris-supported phakic lenses (Verisyse) for treating moderately high myopia.

Methods This prospective clinical study included 40 eyes from 29 patients, who underwent implantation of Verisyse for correction of myopia from -6.00 to -14.50 diopters (D) in the Eye Clinic ''Svjetlost'', Sarajevo, from January 2011 to January 2014. Uncorrected distance visual acuity (UDVA), manifest residual spherical equivalent (MRSE), postoperative astigmatism, intraocular pressure (IOP), endothelial cell (EC) density were evaluated at one, three, six and twelve months. Corrected visual acuity (CDVA), index of safety and efficacy were evaluated after 12 months.

Results Out of 29 patients 15 were males and 14 females, with mean age of 27.9 ± 5.0. After 12 months 77.5% eyes had UDVA ≥ 0.5 and 32.5% had UDVA ≥ 0.8. Mean MRSE was 0.55D ± 0.57D and mean postoperative astigmatism -0.86D ± 0.47D. Efficacy index was 1.09 ± 0.19 and safety index 1.18 ± 0.21. One eye (2.5%) lost two Snellen lines and three eyes (7.5%) one line, 11 eyes (27.5%) gained one line, and five eyes (15.5%) gained two lines. EC loss after 12 months was 7.59 ± 3.05%. There was no significant change of IOP after one year follow up.

Conclusion Implantation of iris-supported phakic lenses (Verisyse) for treating moderately high myopia is an efficient and safe procedure.

Keywords: refractive surgery, diopter, refractive intraocular lens

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INTRODUCTION

The Verisyse phakic intraocular lens (pIOL) was approved in 2004 by the US Food and Drug Administration (FDA) for correction of moderate-to-high myopia (1). The Verisyse, manufactured by Abbott Medical Optics (Santa Ana, CA, USA), is reported to provide excellent refractive outcomes, predictability, and stability, with few complications (2). However, several severe complication have been reported including corneal decompensation (3), intraocular pressure (IOP) elevation (4), dislocation of pIOL, cataract formation (5) and retinal detachment (6).

The Verisyse lens is made of rigid ultraviolet absorbing polymethylmethacrylate (PMMA) material and has an optic diameter of five or six mm. The lens is placed into the anterior chamber and attached to the anterior surface of the iris with haptic clips by enclavation. The rigid nature of the lens requires a 5.5- to 6.5-mm incision, depending on the optic size of the lens. The 5.0 mm lens is available in a diopter range of -3 to -23.50 D and the six mm lens available in diopter range -3 to -15.50 D in 0.5 D steps with <2.50 D of astigmatism (7).

Myopia is a rising problem of a modern society. Phakic intraocular lenses (IOLs) may be a safe and effective alternative for patients with myopia who may not be suitable candidates for excimer laser procedures (8).

The aim of this study was to evaluate efficacy and safety of iris-supported phakic lenses (Verisyse) for treating moderately high myopia for the patients who cannot tolerate wearing contact lenses and glasses because of their high diopter and want a surgical solution for their problem.

PATIENTS AND METHODS

Patients and study design

This investigation was approved by the Ethics Committee at Eye Clinic ''Svjetlost'', Sarajevo. The Tenets of the Helsinki Agreement were followed throughout. All patients signed informed consent for the study.

This prospective clinical study included 40 eyes from 29 patients who underwent implantation of Verisyse for correction of myopia from -6.00 D to -14.50 D in Eye Clinic ''Svjetlost'' Sarajevo from January 2011 to January 2014.

Each patient included in this study had stable myopia for two years and a contraindication for corneal refractive surgery. Anterior chamber depth (ACD) was ≥ three mm, endothelial cell (EC) count was ≥ 2300 cells/mm^2, mesopic pupil ≤ 6.5 mm, astigmatism ≤ 2.5D.

Exclusion criteria were: patients younger than 21, active pathology of the eye, cataract, glaucoma, chronic or recurrent uveitis, prior operative procedure, macular and retinal pathology, autoimmune systemic diseases, diabetes, pregnancy.

Methods

Preoperative examination included: uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) (which are shown in decimal Snellen values), manifest and cycloplegic refraction using autorefractometer (Rexxam Co., Ltd., Kagava, Japan), IOP (Ato Non-Contact Tonometar, Reichert Inc., Buffalo, NY, USA), biomicroscopic examination (Construction Strumenti Oftalmicy - CSO, Florence, Italy), fundus examination, corneal topography (Wavelight, Allegreto Oculyser, Erlangen, Germany), EC count (Specular CSO, Florence, Italy), and pupil size (Pupilographer, Florence, Italy).

Calculation of the pIOL power was performed using software provided by manufacturer (AMO), with target of emmetropia. When the emmetropic lens was not available (because of 0.50 D steps in lenses), slight myopia was preferred. All operative procedures were done by one surgeon.

Six mm optic of Verisyse was used, so the corneal incision of 6.2 mm was centered at 12h. Two vertical paracentesis were performed at two and ten o'clock. After the intracameral injection of myotic and viscoelastic material the lens was implanted in anterior chamber. Phacic IOL was fixed with enclavation needle on three and nine o'clock position on iris. After peripheral iridectomy and removal of viscoelastic material 10-0 nylon sutures were performed along corneal incision. Beginning at week 6 postoperatively over a period of three months sutures were removed, depending on postoperative astigmatism.

One and seven days after the surgery, UDVA, IOP and biomicroscopic examination were recorded. At other testing intervals (one, three, six and 12 months), a complete examination was performed, which included refraction, manifest residual sphe-

rical equivalent (MRSE), corneal topography and EC count also. Corrected distance visual acuity (CDVA), index of safety and efficacy were evaluated after 12 months. Efficacy index is defined as UDVA postoperatively on 12 month/CDVA preoperatively.Safety index is defined as CDVA postoperatively on 12 months /CDVA preoperatively.

Statistical analysis

The comparisons between the preoperative and postoperative periods were performed with the Wilcoxon signed rank test.Value of $p<0.05$ was considered statistically significant.

RESULTS

In this study visual and refractive outcomes of 40 eyes from 29 patients, who underwent implantation of Verisyse, were described. Of these patients 51.7% (15/29) were males and 48.3% (14/29) females. Out of 29 patients 18 underwent monocular and 11 binocular Verisyse implantation.

Mean age was 27.5 ± 5.0 (21-40) years. Preoperative mean UDVA was 0.026 ± 0.02, and mean CDVA 0.6 ± 0.2. Mean preoperative sphere was -10.87D ± 2.56D (from -14.50D to -6.00D). Mean astigmatism was -1.25 D ± 0,6D (from -2.25D to -0.25D). Mean SE preoperatively was -11.48 D ± 2.58D. Mean Verisyse lens power was -11.63 ± 2.67D. Mean ACD was 3.63 ± 0.27 mm. Preoprative mean EC was 2627.32 ± 179.84. Intraocular pressure preoperatively was 16.27 ± 2.29 mmHg.

One year after the surgery the percent of the eyes with UDVA ≥ 0.5 was 77.5% and UDVA of ≥ 0.8 was 32.5%. Statistically significant progression of UDVA between measurement intervals in the first six months was found ($p<0.005$), after which there was no statistically significant change($p=0.152$) (Figure 1).

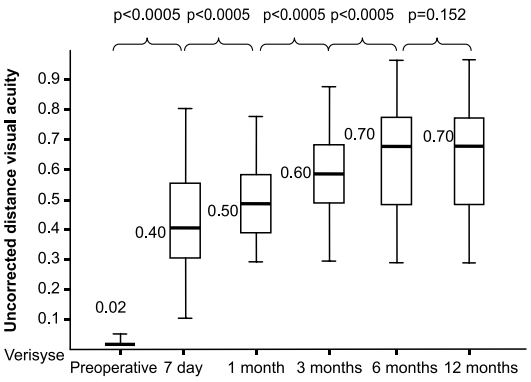

Figure 1. Uncorrected visual acuity (UDVA) values in a 12-month period

The MRSE values drop significantly one month after the treatment to -1.13 D (ranging -1.38 to -0.38D) compared to -12.06D preoperatively ($p<0.005$), and stay stable without statistically significant change over the follow up period (Figure 2).

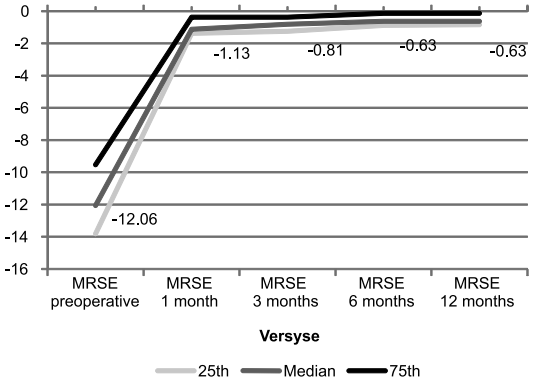

Figure 2. Manifest residual sphere equivalent (MRSE) values in a 12-month period

There was statistically significant change in postoperative astigmatism in the first 6 months and after thatperiod the values remained stable with no statistically significant change ($p>0.005$) (Figure 3).

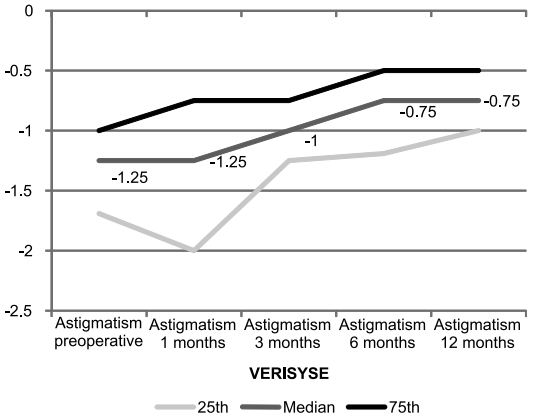

Figure 3. Postoperative astigmatism in a 12-month period

After 12 months 70% of the operated eyes (28/40) were within +-1D. Efficacy index was 1.09±0.79 and index of safety 1.18±0.21. One eye (2.5%) lost two Snellen lines and three eyes (7.5%) one line, 11 eyes (27.5%) gained one line, and five eyes (15.5%) gained two lines.

The EC loss after 12 months was 7.59±3.05%. The loss of endothelial cells was the biggest in first postoperative month (5.23±2.61%)($p<0.005$) (Figure 4).

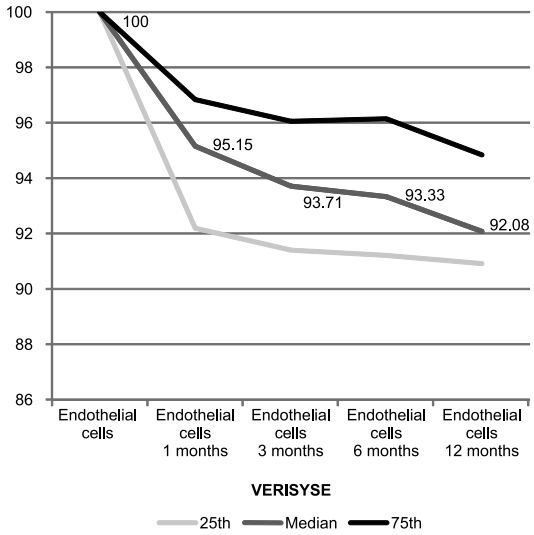

Figure 4. Endothelial cells (EC) loss in a 12-month period

On the first day after the surgery there was a statistically significant elevation of IOP (p=0.003). There was no statistically significant change of IOP during the follow-up period of 12 months (Table 1). There were no intraoperative complications during the procedure, postoperative complications were IOP elevation in five eyes (12.5%), subclinical inflammation in two eyes (5%), cataract formation in one eye (2.5%), pigment dispersion in three eyes (7.5%) and pupil ovalization in three eyes (7.5%).

Table 1. Intraocular pressure (IOP) in 40 eyesin a 12-month period

	Intraocular pressure (mmHg)					
Period after surgery	**Mean**	**S.D.**	**Min.**	**Max.**	**Median**	**p**
0	16.28	2.30	12.00	20.00	16.00	
1 day	17.98	4.22	6.00	27.00	18.00	0.012*
7 days	18.38	2.33	9.00	24.00	18.50	0.442†
1 month	16.90	2.33	12.00	22.00	17.00	0.0001‡
3 months	15.75	3.04	1.00	20.00	16.00	0.022¶
6 months	16.18	1.84	12.00	20.00	16.50	0.376#
12 months	15.65	1.67	12.00	19.00	15.50	0.053§

*0-1day; †1-7days; ‡7days-1 months; ¶1-3 months; #3-6 months; §6-12 months

DISCUSSION

The results of this study have shown significant differences in the values of UDVA, MRSE and postoperative astigmatism in period of the first six months. After this period the values remain constant. This is the result of sutures removal from six weeks to three months postoperatively. Sutures removal has direct effect on lowering postoperative astigmatism, which consequently reflects in lowering of MRSE through first six months (9). Maloney et al. also reported a decrease in postoperative astigmatism of 0.3De in first six months of the study (10). Coullet et al. (11) stated that MRSE values were stable after sutures removal, on 12 months follow up and the values were -1.01± 0.69D. Budoet al. (12) reported 76.8% of eyes had UDVA ≥ 0.5 and Gierek-Ciaciura (13) 80% of the eyes, which is similar to our results (77.5%).

The results of this study have shown that one eye (2.5%) lost two Snellen lines and three eyes (7.5%) one line, 11 eyes (27.5%) gained one line, and five eyes (15.5%) gained two lines. Similarily to our results Coulet reported 9.7 % eyes lost two Snellen lines, 22.6 % gained one line and 25.8 % gained two or more lines (11). Eyes which gained Snellen lines were high amblyopes in our investigation, and the gain of lines can be explained with magnification of image on retina after pIOL implantation compared to image on retina with glasses correction especially in high myopes. Also, it is possible that the aberrations from correction glasses can contribute to lower visual acuity, and these are avoided after pIOL implantation. In our study loss of Snellen lines was a result of postoperative astigmatism (three eyes) and CNV formation (one eye).

In our study efficacy index was 1.09. Budo reported 1.03 (12), Menezo 0.95 (5), Senthil 0.93 (14). Safety was 1.18. Malecase (15) reported safety index of 1.12, Coulett 1.13 (11). Our results do not differ from other studies.

Disadvantages of this procedure include risks that follow other intraoperative procedures, but also risks related to the lens itself such as, for example, cataract formation, endothelial cell loss, subclinical inflammation, rise of intraocular pressure (IOP), pupil ovalization, pigment dispersion, postoperative astigmatism (16).

Two eyes (5%) in this study had subclinical inflammation postoperatively, which was controlled using topical steroid therapy within one month. In FDA clinical study it was 5.2%, which is very similar to our study (17). One eye (2.5%) had opacification of anterior cortex and as a consequence loss of one Snellen line after 12 months. This complication can occur due to surgical trauma. Sanders, Stulting and Menzo reported that 3% of the cases had cataract formation (4,5,18). Pigment

dispersion can be found on the surface of pIOL and is usually combined with IOP elevation. In our study three eyes (7.5%) had pigment dispersion, but with no consequences on visual acuity, three eyes (7.5%) had pupil ovalization and only one case (2.5%) had optical phenomena in night vision. Maloney study(10) reported that 14.0% of cases had pupillary irregularities. The EC loss in our study after 12 months was 7.59 ± 3.0%, and the biggest loss was in the first postoperative month 5.23 ± 2.6%. The reasons for this can be surgical trauma and postoperative subclinical inflammation (7). Coulet (11) reported EC loss of 9.4% after 12 months, and Gierek (13) 6.8%. Usually EC loss and consecutive decompensation of endothelium that leads to bullous keratopathy can be caused by illness of the cornea, trauma but also by anoperative procedure (19).

Postoperative elevation of IOP was observed in 12.5 % of eyes (one patient binocular, three patients monocular). In all cases IOP could be regulated with topical antiglaucoma drops, the therapy was excluded within five weeks of surgery. This early postoperative elevation of IOP can be explained with the residual viscoelastic, or the patient can be corticosteroid responder (7).

Complications described in the literature occur in low percentages, which makes the implantation of these lenses a safe procedure (19). In this study no other postoperative complications were documented, although in other studies pIOL dislocation and retinal detachment were reported (20).Our clinical results show that Verisyse implantation is a safe and effective procedure for treating moderately high myopia with one year follow-up. Therefore,Verisyse is a good alternative for patients with myopia, who are not suitable candidates for excimer laser procedures.

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TRASPARENCY DECLARATION

Competing interests: None to declare.

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Efikasnost i sigurnost iris-fiksirajućih fakičnih leća (Verisyse) za tretman srednjevisoke miopije

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SAŽETAK

Cilj Evaluirati efikasnost i sigurnost iris-fiksirajućih fakičnih leća (*Verisyse*) za tretman srednje visoke miopije.

Metode Prospektivna klinička studija obuhvatila je 40 očiju od 29 pacijenata koji su bili podvrgnuti implantaciji *Verisyse* lećâ, zbog korekcije miopije u iznosu od -6.00 D do -14.00 D, u Poliklinici "Svjetlost" Sarajevo, od januara 2011. do januara 2014. godine. Nekorigovana vidna oštrina za daljinu (UDVA), manifestni rezidualni sferni ekvivalent (MRSE), postoperativni astigmatizam, intraokularni pritisak (IOP) te gustoća endotelnih ćelija (EC) evaluirani su na jedan, tri, šest i 12 mjeseci. Korigovana vidna oštrina (CDVA), indeks sigurnosti i efikasnosti evaluirani su nakon 12 mjeseci.

Rezultati Od 29 pacijenata 15 su bili muškarci, a 14 žene, sa srednjom vrijednosti godina 27,9 (±5,0). Nakon 12 mjeseci 77,5% očiju imali su UDVA ≥ 0.5, a 32,5% je imalo UDVA ≥ 0.8. Srednja vrijednost MRSE bila je 0,55 D ± 0,57 D, a srednja vrijednost postoperativnog astigmatizma bila je -0,86 D ± 0,47 D. Indeks efikasnosti je iznosio 1,09 ± 0,19 a indeks sigurnosti 1,18 ± 0,21. Jedno oko (2,5%) je izgubilo dvije Snellenove linije, a tri oka (7,5%) jednu liniju; 11 očiju (27,5%) je dobilo jednu liniju, a pet očiju (15,5%) dobilo je dvije linije. Gubitak endotelnih ćelija, nakon 12 mjeseci, iznosio je 7,59 ± 3,05%. Nije bilo statistički značajne promjene u visini očnog pritiska u toku perioda praćenja.

Zaključak Implantacija iris-fiksirajućih fakičnih leća (*Verisyse*) je efikasna i sigurna metoda za tretman srednje visoke miopije.

Ključne riječi: refraktivna hirurgija, dioptrija, refraktivne intraokularne leće